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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 905

[Docket No. FV04–905–3 FIR]

Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Limiting the Volume of Small Red Seedless Grapefruit

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule removes the weekly percentages established for the first 22 weeks of the 2004–05 season beginning September 20, 2004. The Citrus Administrative Committee voted to take this action following the crop losses the industry sustained from Hurricanes Charley, Frances, and Jeanne. It is expected that this action will provide more red seedless grapefruit for shipment to the fresh fruit market.

DATES: Effective February 5, 2005.

FOR FURTHER INFORMATION CONTACT: Doris Jamieson, Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 799 Overlook Drive, Suite A, Winter Haven, Florida 33884; Telephone: (863) 324–3375; Fax: (863) 325–8793; or George Kelhart, Technical Advisor, 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.

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 rule is issued under Marketing Agreement No. 84 and Marketing Order No. 905, both as amended (7 CFR part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, hereinafter referred to as the ''order.'' The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

USDA is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule removes the weekly percentages established for the first 22 weeks of the 2004–05 season beginning September 20, 2004. This rule 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 rule terminates an interim final rule published in the **Federal Register** on August 16, 2004 (69 FR 50269) which established limits on the volume of small red seedless grapefruit entering the fresh market. This rule removes the weekly percentages established for the first 22 weeks of the 2004–05 season beginning September 20, 2004. The Committee voted to terminate this action following its crop losses from Hurricanes Charley, Frances, and Jeanne. It is expected that this action will provide more red seedless grapefruit for shipment to the fresh fruit market.

Section 905.52 of the order provides authority to limit shipments of any grade or size, or both, of any variety of Florida citrus. Such limitations may restrict the shipment of a portion of a specified grade or size of a variety. Under such a limitation, the quantity of such grade or size a handler may ship during a particular week is established as a percentage of the total shipments of such variety shipped by that handler during a prior period, established by the Committee and approved by USDA.

Section 905.153 of the regulations provides procedures for limiting the volume of small red seedless grapefruit entering the fresh market. The procedures specify that the Committee may recommend that only a certain percentage of sizes 48 and 56 red seedless grapefruit be made available for shipment into fresh market channels for any week or weeks during the regulatory period. The regulation period is 22 weeks long and begins the third Monday in September. Under such limitation, the quantity of sizes 48 and 56 red seedless grapefruit that may be shipped by a handler during a regulated week is calculated using the recommended percentage.

An interim final rule was published in the **Federal Register** which limited the volume of sizes 48 (3$^{9}/_{16}$ inches minimum diameter) and 56 (3$^{5}/_{16}$ inches minimum diameter) red seedless grapefruit entering the fresh market by instituting weekly percentages for the first 22 weeks of the 2004–05 season. The rule established weekly percentages at 45 percent for the first three weeks (September 20, 2004 through October 10, 2004, 36 percent for weeks 4 through 18 (October 11, 2004 through January 23, 2005), 40 percent for weeks 19 and 20 (January 23, 2005 through February 6, 2005), and 45 percent for weeks 21 and 22 (February 7, 2005 through February 20, 2005). The Committee recommended this action unanimously at a meeting June 15, 2004. Similar limitations were implemented during the previous seven seasons.

On August 13, 2004, Hurricane Charley hit the west coast of Florida, doing considerable damage to the 2004 citrus crop. On September 5, 2004, Hurricane Frances hit the east coast of

Florida, the primary growing region for red seedless grapefruit. Again, there was a great deal of damage to the citrus industry. Then on September 26, 2004, Hurricane Jeanne hit Florida, nearly following the same path as Hurricane Frances, further damaging the citrus crop. The extent of the loss is evident in the official USDA crop estimate for grapefruit during the 2004–05 season. The estimate is now 13 million 4/5 bushel cartons. This is about 70 percent less than last year's estimate.

At its November 16, 2004, meeting, the Committee discussed the percentage of size rule which went into effect on September 20, 2004. The percentage of size regulation helps reduce the detrimental market effects of small-sized red seedless grapefruit over-supplies. With the loss of so much of the red seedless grapefruit crop due to the hurricanes, the Committee believes that a percentage size regulation for 2004–05 is not needed. In fact, the Committee believes that there may be an insufficient amount of fruit to supply the demand for fresh fruit. There will be less large-sized red seedless grapefruit in 2004–05, so more of the smaller sizes will be needed to supply consumer demand. Consequently, the reasons for regulating the amount of small red seedless grapefruit entering the fresh market during the 2004–05 season are no longer applicable.

Therefore, the Committee unanimously recommended terminating the rule currently in effect.

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 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 the 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 75 grapefruit handlers subject to regulation under the order and approximately 11,000 growers of citrus in the regulated area. Small agricultural service firms, including handlers, are defined by the Small Business Administration (SBA) as those having annual receipts of less than $5,000,000, and small agricultural producers are defined as those having annual receipts of less than $750,000 (13 CFR 121.201).

Based on industry and Committee data, the average annual f.o.b. price for fresh Florida red seedless grapefruit during the 2003–04 season was approximately $7.58 per 4/5-bushel carton, and total fresh shipments for the 2003–04 season are estimated at 24.7 million cartons of red grapefruit. Approximately 25 percent of all handlers handled 75 percent of Florida's grapefruit shipments. Using the average f.o.b. price, at least 80 percent of the grapefruit handlers could be considered small businesses under SBA's definition. Therefore, the majority of Florida grapefruit handlers may be classified as small entities. The majority of Florida grapefruit producers may also be classified as small entities.

This rule terminates an interim final rule published in the **Federal Register** on August 16, 2004, (69 FR 50269) which set limits on the volume of small red seedless grapefruit entering the fresh market. The interim final rule established weekly percentages in § 905.350 for the first 22 weeks of the 2004–05 season beginning September 20, 2004, under the provisions of § 905.153. Authority for this action is provided in § 905.52. USDA may terminate a regulation if it does not tend to effectuate the declared policy of the Act. The Committee unanimously voted to terminate the interim final rule and the percentage size regulation at a meeting held on November 16, 2004.

During the months of August and September the major grapefruit growing regions in Florida suffered significant damage and fruit loss from multiple hurricanes. The strong winds from the storms blew substantial volumes of the setting fruit off the trees. The impact of the storms also produced a much higher than normal fruit drop. The extent of the loss is evident in the official USDA crop estimate supplied for this season which reflects a 70 percent decrease from last year's estimate. With the available volume of red seedless grapefruit substantially reduced, there is no longer any need to regulate volume for the 2004–05 season. Consequently, the Committee voted to terminate this action. This action will not create any additional costs for growers or handlers.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large citrus handlers. 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. In addition, as noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Committee's meetings were widely publicized throughout the citrus industry and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the June 15, 2004, and November 16, 2004, meetings were public meetings and all entities, both large and small, were able to express their views on this issue.

An interim final rule concerning this action was published in the **Federal Register** on August 16, 2004. Copies of the rule were mailed by the Committee's staff to all Committee members and grapefruit handlers. In addition, the rule was made available through the Internet by USDA and the Office of the Federal Register. That rule provided for a 30-day comment period which ended September 15, 2004. One comment was received.

The commenter expressed concern that limiting the volume of grapefruit in order to raise prices negatively affected the consumer. The comment has been noted. However, the Committee has recommended terminating this action, effectively eliminating volume regulations for the 2004–05 season. Therefore, no changes will be made as a result of the comment.

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 material presented, including the Committee's recommendation, and other information, it is found that terminating the interim final rule, as published in the **Federal Register** (69 FR 502769, August 16, 2004) will tend to effectuate the declared policy of the Act. Further, it also is found that implementation of the percentage size regulation during the 2004–05 season would not effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because this rule terminates percentage size regulations which were not needed for the first 22 weeks of the 2004–05 shipping season.

List of Subjects in 7 CFR Part 905

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements, Tangelos, Tangerines.

■ For the reasons discussed in the preamble, 7 CFR Part 905 is amended as follows:

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

■ 1. The authority citation for part 905 continues to read as follows:

Authority: 7 U.S.C. 601–674.

§ 905.350 [Removed and reserved]

■ 2. Section 905.350 is removed and reserved.

Dated: January 31, 2005.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 05–2154 Filed 2–3–05; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19201; Directorate Identifier 2003–NM–100–AD; Amendment 39–13959; AD 2005–03–03]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200, –300, and –300F Series Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is superseding an existing airworthiness directive (AD), which applies to all Boeing Model 767–200, –300, and –300F series airplanes. That AD currently requires examination of maintenance records to determine if Titanine JC5A (also known as Desoto 823E508) corrosion inhibiting compound (''C.I.C.'') was ever used; inspection for cracks or corrosion and corrective action, if applicable; repetitive inspections and C.I.C. applications; and modification of the aft trunnion area of the outer cylinder, which terminates the need for the repetitive inspections and C.I.C. applications. This new AD also requires, for certain other airplanes, repetitive inspections for cracks or corrosion, corrective action if necessary, and repetitive C.I.C. applications. This AD is prompted by a report that JC5A was used on more airplanes during production than previously identified. We are issuing this AD to prevent severe corrosion in the main landing gear (MLG) outer cylinder at the aft trunnion, which could develop into stress corrosion cracking and consequent collapse of the MLG.

DATES: This AD becomes effective March 11, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of March 11, 2005.

On May 6, 2002 (67 FR 19322, April 19, 2002), the Director of the Federal Register approved the incorporation by reference of a certain other publication.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. You can examine this information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2004–19201; the directorate identifier for this docket is 2003–NM–100–AD.

FOR FURTHER INFORMATION CONTACT: Suzanne Masterson, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6441; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) with an AD to supersede AD 2002–08–07, amendment 39–12715, (67 FR 19322, April 19, 2002). The existing AD applies to all Boeing Model 767–200, –300, and –00F series airplanes. The proposed AD was published in the **Federal Register** on September 29, 2004 (69 FR 58103). That action proposed to continue to require examination of maintenance records to determine if Titanine JC5A (also known as Desoto 823E508) corrosion inhibiting compound (''C.I.C.'') was ever used; inspection for cracks or corrosion and corrective action, if applicable; repetitive inspections and C.I.C. applications; and modification of the aft trunnion area of the outer cylinder, which terminates the need for the repetitive inspections and C.I.C. applications. The action also proposed to require, for certain other airplanes, repetitive inspections for cracks or corrosion, corrective action if necessary, and repetitive C.I.C. applications.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD.

Support for the Proposed AD

One commenter supports the proposed AD.

Request To Add Compliance Statement

One commenter requests that we add the verbiage, ''required as indicated, unless accomplished previously,'' to the compliance section of the proposed AD. The commenter believes this statement is needed to obtain credit for the inspections and repetitive C.I.C applications it accomplished, prior to issuance of the proposed AD, on its airplanes in accordance with Boeing Alert Service Bulletin 767–32A0192, Revision 1, dated March 13, 2003.

We partially agree, since similar language to that suggested by the commenter is found in paragraph (e) of this AD. As part of our effort to use plain language in ADs, we have rewritten the compliance statement as follows: ''You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.'' While the language has changed, the intent of the statement is the same. Therefore, no further change to this AD is necessary in this regard.

Request To Add Credit for Previous Accomplishment

One commenter requests that we add a note to the proposed AD, which would give credit for work accomplished in compliance with AD 2002–08–07. The commenter suggests the following note, or language similar to this: ''Accomplishment of the actions required by paragraph[s] (a) through (l) of AD 2002–08–07 amendment 39–12715, is acceptable for compliance

with the requirements of paragraph[s] (g) through (r) of this AD. This AD does not require that those actions be repeated.'' We infer that the commenter believes the proposed AD, as written, would require repeating work the commenter has already accomplished.

We do not agree that a credit note is necessary because paragraph (e) of this AD, as discussed in the first comment, already gives credit for any work previously accomplished. Operators should note that the new requirements of paragraph (s) of this AD are applicable only to Boeing Model 767–200, –300, and –300F series airplanes, with line numbers (L/Ns) 834 through 874 inclusive. Furthermore, if an operator previously accomplished these new required actions on any applicable airplane (L/Ns 834 through 874 inclusive), then that airplane is also in compliance, as stated in paragraph (e) of this AD. Therefore no change to this AD is necessary in this regard.

Explanation of Change to This AD

Boeing has received a Delegation Option Authorization (DOA). We have revised this final rule to delegate the authority to approve an alternative method of compliance for any repair required by this AD to the Authorized Representative for the Boeing DOA Organization rather than the Designated Engineering Representative (DER).

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD with the change described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

There are about 848 airplanes of the affected design in the worldwide fleet. This AD will affect about 357 airplanes of U.S. registry. The new requirements of this AD add no additional economic burden for operators affected by AD 2002–08–07. The current costs for this AD are repeated for the convenience of affected operators, as follows:

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Fleet cost
C.I.C. Application	1	$65	None	$65, per application cycle.	$23,205 per application cycle.
Cross Bolt Hole Inspection—Bushings Removed.	2	65	None	130	46,410.
Restoration for Bushings Removed	6	65	None	390	139,230.
Cross Bolt Inner Chamfer Inspection—Bushings Not Removed.	2	65	None	130, per inspection cycle.	46,410, per inspection cycle.
Restoration for Bushings Not Removed	6	65	None	390	139,230.
Terminating Action	64	65	$6,356	10,516	3,754,212.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing amendment 39–12715 (67 FR 19322, April 19, 2002), and by adding the following new airworthiness directive (AD):

2005–03–03 Boeing: Amendment 39–13959. Docket No. FAA–2004–19201; Directorate Identifier 2003–NM–100–AD.

Effective Date

(a) This AD becomes effective March 11, 2005.

Affected ADs

(b) This AD supersedes AD 2002–08–07, amendment 39–12715 (67 FR 19322, April 19, 2002).

Applicability

(c) This AD applies to all Boeing Model 767–200, –300, and –300F series airplanes, certificated in any category.

Unsafe Condition

(d) This AD was prompted by a report that Titanine JC5A (also known as Desoto 823E508) was used on more airplanes during

production than previously identified. We are issuing this AD to prevent severe corrosion in the main landing gear (MLG) outer cylinder at the aft trunnion, which could develop into stress corrosion cracking and consequent collapse of the MLG.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Requirements of AD 2002–08–07, Amendment 39–12715

Line Numbers (L/N) 1 Through 833 Inclusive, and 875 and Subsequent

(f) For airplanes with L/Ns 1 through 833 inclusive, and 875 and subsequent: Do the actions specified in paragraphs (g) through (q) of this AD, as applicable.

Records Examination

(g) Within 90 days after May 6, 2002 (the effective date of AD 2002–08–07, amendment 39–12715), examine airplane records to determine if Titanine JC5A or Desoto 823E508 (hereafter collectively referred to as ''JC5A'') corrosion inhibiting compound (''C.I.C.'') was used in the aft trunnion area of the MLG outer cylinder during general maintenance, overhaul, or incorporation of Boeing Alert Service Bulletin 767–32A0148, dated December 21, 1995, Revision 1, dated October 10, 1996 (required by paragraph (e) of AD 96–21–06, amendment 39–9783), or Revision 2, dated November 30, 2000; in accordance with Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Revision 1, dated March 13, 2003. If records do not show conclusively which compound was used, assume JC5A was used. Refer to Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001, for the line numbers of airplanes that were assembled new using JC5A.

Note 1: Prior to January 31, 2001, if BMS 3–27 was ordered from Boeing, Boeing shipped JC5A as a substitute.

MLGs on Which JC5A Was Not Used

(h) Except as provided by paragraph (p) (''Use of JC5A Prohibited'') of this AD, if, according to the criteria of paragraph (g) of this AD, JC5A was never used, no further action is required by this AD.

C.I.C. Applications, Inspections, and Corrective Actions if Necessary

(i) For Category 1 MLG outer cylinders as identified in Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001: If, according to the criteria of paragraph (g) of this AD, JC5A may have been used, perform the actions specified in both paragraphs (j) and (k) of this AD, as applicable, in accordance with Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Revision 1, dated March 13, 2003.

(j) For MLGs and MLG outer cylinders identified in paragraphs (j)(1), (j)(2), and (j)(3) of this AD: Within 90 days after May 6, 2002, perform the C.I.C. application on the MLG in accordance with ''Part 3—C.I.C. Application'' of the Accomplishment Instructions of Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Revision 1, dated March 13, 2003. Thereafter, repeat at intervals not to exceed 180 days until the terminating action required by paragraph (q) of this AD has been accomplished.

(1) MLG outer cylinders that are less than 3 years old since new.

(2) MLGs that have been overhauled less than 3 years before May 6, 2002.

(3) MLGs on which rework per Boeing Alert Service Bulletin 767–32A0148, dated December 21, 1995; Revision 1, dated October 10, 1996; or Revision 2, dated November 30, 2000, was accomplished less than 3 years before May 6, 2002.

(k) Before the MLG outer cylinder is 3 years old since new, since last overhaul, or since rework per Boeing Alert Service Bulletin 767–32A0148, dated December 21, 1995; Revision 1, dated October 10, 1996; or Revision 2, dated November 30, 2000; or within 90 days after May 6, 2002; whichever is later; perform a detailed inspection for cracks and corrosion of the cross bolt bushing holes and chamfers in accordance with ''Part 1—Cross Bolt Hole Inspection—Bushings Removed'' of the Accomplishment Instructions of Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Revision 1, dated March 13, 2003.

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

(1) If no crack or corrosion is found during the detailed inspection required by paragraph (k) of this AD, perform the actions in paragraphs (k)(1)(i), (k)(1)(ii), and (k)(1)(iii) of this AD, at the applicable times indicated.

(i) Before further flight, perform the restoration steps shown in Figure 2 of the service bulletin; and thereafter at intervals not to exceed 180 days, perform the C.I.C. application on the landing gear in accordance with ''Part 3—C.I.C. Application'' of the Accomplishment Instructions of the service bulletin.

(ii) Within 18 months after performing the detailed inspection required by paragraph (k) of this AD, and thereafter at intervals not to exceed 18 months, perform the detailed inspection for cracks and corrosion of the cross bolt hole inner chamfer, in accordance with ''Part 2—Cross Bolt Hole Inner Chamfer Inspection—Bushings Not Removed'' of the Accomplishment Instructions of the service bulletin, until the terminating action required by paragraph (q) of this AD has been accomplished.

(iii) Before the MLG cylinder is 6½ years old since new, since last overhaul, or since rework per Boeing Alert Service Bulletin 767–32A0148, dated December 21, 1995; Revision 1, dated October 10, 1996; or Revision 2, dated November 30, 2000; whichever is later; perform the terminating action described in paragraph (q) of this AD.

(2) If any corrosion is found on the cross bolt holes or outer chamfers during the detailed inspection required by paragraph (k) of this AD, before further flight, remove the corrosion per Figure 2 of the service bulletin.

(i) If all of the corrosion can be removed: Before further flight, perform the restoration steps shown in Figure 2 of the service bulletin; thereafter at intervals not to exceed 180 days, perform the C.I.C. application on the MLG in accordance with ''Part 3—C.I.C. Application'' of the Accomplishment Instructions of the service bulletin; and perform the terminating action described in paragraph (q) of this AD, at the applicable time specified in paragraph (k)(2)(i)(A) or (k)(2)(i)(B) of this AD.

(A) If the MLG outer cylinder is less than 5 years old since new, if the MLG was last overhauled less than 5 years before May 6, 2002, or if rework per Boeing Alert Service Bulletin 767–32A0148, dated December 21, 1995; Revision 1, dated October 10, 1996; or Revision 2, dated November 30, 2000; was accomplished less than 5 years before May 6, 2002: Within 18 months after performing the detailed inspection required by paragraph (k) of this AD.

(B) If the MLG outer cylinder is 5 years old or more since new, if the MLG was last overhauled 5 years or more before May 6, 2002, or if rework per Boeing Alert Service Bulletin 767–32A0148, dated December 21, 1995; Revision 1, dated October 10, 1996; or Revision 2, dated November 30, 2000; was accomplished 5 years or more before May 6, 2002: Before the MLG outer cylinder is 6½ years old since new, since last overhaul, or since rework per Boeing Alert Service Bulletin 767–32A0148, dated December 21, 1995; Revision 1, dated October 10, 1996; or Revision 2, dated November 30, 2000; whichever is later.

(ii) If any corrosion cannot be removed, before further flight, perform the terminating action described in paragraph (q) of this AD.

(3) If any crack is found anywhere during the detailed inspection required in paragraph (k) of this AD, or if corrosion in the inner cross bolt hole chamfers is found, before further flight, perform the terminating action described in paragraph (q) of this AD.

(l) For Category 2 MLG outer cylinders as identified in Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001: If, according to the criteria of paragraph (g) of this AD, JC5A may have been used, perform the actions specified in both paragraphs (m) and (n) of this AD, as applicable, in accordance with Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Revision 1, dated March 13, 2003.

(m) For MLGs and MLG outer cylinders identified in paragraphs (m)(1) and (m)(2) of this AD: Within 90 days after May 6, 2002, perform the C.I.C. application on the MLG in accordance with ''Part 3—C.I.C. Application'' of the Accomplishment Instructions of Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Revision 1, dated March 13, 2003. Thereafter, repeat the application at intervals not to exceed 180 days until the terminating action required by paragraph (q) of this AD has been accomplished.

(1) MLG outer cylinders that are less than 3 years old since new.

(2) MLGs that have been overhauled less than 3 years before May 6, 2002.

(n) Before the MLG outer cylinder is 3 years old since new or since the last overhaul, or within 90 days after May 6, 2002, whichever is later, perform a detailed inspection for cracks and corrosion of the cross bolt hole inner chamfer, in accordance with ''Part 2—Cross Bolt Hole Inner Chamfer Inspection—Bushings Not Removed'' of the Accomplishment Instructions of Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Revision 1, dated March 13, 2003.

(1) If no crack or corrosion is found during the inspection required by paragraph (n) of this AD, before further flight, and thereafter at intervals not to exceed 180 days, perform the C.I.C. application on the MLG in accordance with ''Part 3—C.I.C. Application'' of the Accomplishment Instructions of the service bulletin, until the next MLG overhaul. After the next MLG overhaul has been completed, no further action is required by this AD.

(2) If any corrosion is found during the detailed inspection required by paragraph (n) of this AD, before further flight, remove the cross bolt bushings and perform the detailed inspection specified in paragraph (k) of this AD, and remove the corrosion per Figure 2 of the service bulletin.

(i) If all of the corrosion can be removed, perform the actions specified in paragraph (n)(2)(i)(A) and (n)(2)(i)(B) of this AD, at the applicable times indicated.

(A) Prior to further flight, perform the restoration steps shown in Figure 2 of the service bulletin; and thereafter at intervals not to exceed 180 days, perform the C.I.C. application on the MLG in accordance with ''Part 3—C.I.C. Application'' of the Accomplishment Instructions of the service bulletin.

(B) Within 18 months after the corrosion removal required by paragraph (n)(2) of this AD, perform the terminating action described in paragraph (q) of this AD.

(ii) If all the corrosion cannot be removed, before further flight, perform the terminating action required by paragraph (q) of this AD.

(3) If any crack is found during the detailed inspection required by paragraph (n) of this AD, before further flight, perform the terminating action described in paragraph (q) of this AD.

Parts Installation

(o) As of May 6, 2002, no person shall install on any airplane an MLG outer cylinder unless maintenance records conclusively show that JC5A has never been used on that MLG outer cylinder, or unless it complies with paragraph (q) of this AD.

Use of JC5A Prohibited

(p) As of May 6, 2002, no person shall use the C.I.C. JC5A in the aft trunnion area of the MLG outer cylinder on any airplane.

Terminating Action

(q) Perform the terminating action (including removal of the existing bushings, repair of the aft trunnion area of the outer cylinder, and machining and installation of new bushings) in accordance with ''Part 4—Terminating Action'' of the Accomplishment Instructions of Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Revision 1, dated March 13, 2003. Completion of the terminating action terminates the requirements for the repetitive inspections and C.I.C. applications of this AD.

Credit for Terminating Action

(r) For all airplanes, accomplishment of the actions specified in paragraph (q) of this AD is considered acceptable for compliance with the requirements of paragraph (e) of AD 2002–01–13, amendment 39–12607.

New Requirements of This AD

L/Ns 834 Through 874 Inclusive

(s) For airplanes with L/Ns 834 through 874 inclusive: Do the actions specified in paragraphs (s)(1), (s)(2), and (s)(3) of this AD.

(1) Within 90 days after the effective date of this AD, and thereafter at intervals not to exceed 180 days: Do the actions specified in paragraph (m) of this AD until the terminating action required by paragraph (q) of this AD has been accomplished.

(2) Before the MLG outer cylinder is 3 years old since new or since last overhaul, or within 90 days after the effective date of this AD, whichever is later: Do the actions as specified in paragraph (n) of this AD.

(3) As of the effective date of this AD, the actions specified in paragraphs (o) and (p) of this AD must be complied with.

Reporting Requirement

(t) Although the service bulletins referenced in this AD specify to submit certain information to the manufacturer, this AD does not include such a requirement.

Alternative Methods of Compliance (AMOCs)

(u)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(v) Unless otherwise specified by this AD, the actions shall be done in accordance with Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001; or Boeing Alert Service Bulletin 767–32A0192, Revision 1, dated March 13, 2003.

(1) The Director of the Federal Register approves the incorporation by reference of Boeing Alert Service Bulletin 767–32A0192, Revision 1, dated March 13, 2003 in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The Director of the Federal Register previously approved the incorporation by reference of Boeing Alert Service Bulletin 767–32A0192, dated May 31, 2001, as of May 6, 2002 (67 FR 19322, April 19, 2002).

(3) For copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on January 21, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–1805 Filed 2–3–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20250; Directorate Identifier 2003–NM–267–AD; Amendment 39–13961; AD 2005–03–05]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–90–30 Airplanes

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

ACTION: Final rule; request for comments.

SUMMARY: The FAA is revising an existing airworthiness directive (AD), which applies to certain McDonnell Douglas Model MD–90–30 airplanes. This AD requires a one-time general visual inspection to detect wire chafing damage and to determine adequate clearance between the disconnect panel structure and the wires above the aft left lavatory; and corrective actions, if necessary. This new AD revises the applicability of the existing AD. This AD is prompted by the determination that certain airplanes unaffected by the existing AD are subject to the unsafe condition, and certain other airplanes should be removed from the applicability. We are issuing this AD to prevent damage to certain wires due to contact between the wires and the adjacent structure, which could result in electrical arcing and consequent smoke and fire in the cabin.

DATES: Effective February 22, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of February 22, 2005.

We must receive comments on this AD by April 5, 2005.

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

- 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.
- Fax: (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 service information identified in this AD, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846; Attention: Data and Service Management, Dept. C1-L5A (D800–0024). You can examine this information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20250; the directorate identifier for this docket is 2003–NM–267–AD.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

FOR FURTHER INFORMATION CONTACT: George Y. Mabuni, Senior Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5341; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: On February 14, 2003, we issued AD 2003–04–10, amendment 39–13058 (68 FR 9513, February 28, 2003), for certain McDonnell Douglas Model MD–90–30 airplanes. That AD requires a one-time general visual inspection to find wire chafing damage and to determine adequate clearance between the disconnect panel structure and the wires above the aft left lavatory; and corrective actions, if necessary. That AD was prompted by a report of uncommanded deployment of cabin oxygen masks due to chafing of certain wires. We issued that AD to prevent damage to certain wires due to contact between the wires and the adjacent structure, which could result in electrical arcing and consequent smoke and fire in the cabin.

Actions Since Existing AD Was Issued

Since we issued AD 2003–04–10, Boeing has revised relevant service information to change the effectivity, as explained in the following section.

Relevant Service Information

AD 2003–04–10 requires accomplishing the actions specified in Boeing Alert Service Bulletin MD90–24A074, Revision 1, dated August 8, 2001. The manufacturer has since issued Revision 02, dated June 3, 2003. Revision 02 revises the effectivity by adding certain airplanes and removing others. The procedures have not changed. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the AD

We have evaluated all pertinent information, identified an unsafe condition that is likely to exist or develop on other products of this same type design, and determined that it is necessary to revise AD 2003–04–10. This new AD retains the requirements of AD 2003–04–10. This new AD revises the applicability by removing certain airplanes and adding other airplanes.

This AD requires using the revised service information described previously to perform these actions, except as discussed under ''Differences Between the AD and the Service Bulletin.''

Differences Between the AD and the Service Bulletin

The service bulletin specifies a compliance time of 120 days after the issue date of Revision 1 of the service bulletin (August 8, 2001). For those airplanes newly added to the applicability in this AD, we have provided a compliance time of 6 months after the effective date of the AD to avoid potentially grounding those airplanes.

Costs of Compliance

There are about 89 airplanes of the affected design worldwide. The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection	1	$65	None required	$65	21	$1,365

The airplanes that are newly added to the applicability of this AD are currently operated by non-U.S. operators under foreign registry; therefore, those airplanes are not directly affected by this AD. If a newly affected airplane is imported and placed on the U.S. Register in the future, the costs provided in the above table would apply.

FAA's Determination of the Effective Date

For U.S.-registered airplanes, the changes in this new AD provide relief from the requirements of AD 2003–04–10, and none of the newly added airplanes is on the U.S. Register. Therefore, providing notice and opportunity for public comment is unnecessary before this AD is issued, and this AD may be made effective in less than 30 days after it is published in the **Federal Register**.

Comments Invited

Although this is a final rule that was not preceded by notice and an opportunity for public comment, we invite you to submit any relevant written data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20250; Directorate Identifier 2003–NM–267–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the AD in light of those comments.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that the regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2005–03–05 McDonnell Douglas: Amendment 39–13961. Docket No. FAA–2005–20250; Directorate Identifier 2003–NM–267–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective February 22, 2005.

Affected ADs

(b) This AD revises AD 2003–04–10, amendment 39–13058 (68 FR 9513, February 28, 2003).

Applicability

(c) This AD applies to McDonnell Douglas Model MD–90–30 airplanes, certificated in any category, as listed in Boeing Alert Service Bulletin MD90–24A074, Revision 02, dated June 3, 2003.

Unsafe Condition

(d) This AD was prompted by our determination that certain airplanes unaffected by AD 2003–04–10, amendment 39–13058, are subject to the unsafe condition, and certain other airplanes should be removed from the applicability of that AD. We are issuing this AD to prevent damage to certain wires due to contact between the wires and the adjacent structure, which could result in electrical arcing and consequent smoke and fire in the cabin.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

One-time Inspection/Corrective Actions

(f) At the applicable time specified in paragraph (f)(1) or (f)(2) of this AD: Do a one-time general visual inspection to find wire chafing damage and to determine adequate clearance between the disconnect panel structure and the wires above the aft left lavatory, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–24A074, Revision 02, dated June 3, 2003. If no damage is found and the clearance is adequate, no further action is required by this AD.

Note 1: For the purposes of this AD, a general visual inspection is: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(1) For airplanes listed in Boeing Alert Service Bulletin MD90–24A074, Revision 1, dated August 8, 2001: Inspect within 12 months after April 4, 2003 (the effective date of AD 2003–04–10).

(2) For airplanes not identified in paragraph (f)(1) of this AD: Inspect within 6 months after the effective date of this AD.

(g) Based on the findings of the inspection required by paragraph (f) of this AD, do the applicable actions specified in paragraph (g)(1) or (g)(2) of this AD before further flight in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–24A074, Revision 02, dated June 3, 2003.

(1) If no damage is found, but the clearance is inadequate: Secure the wires using tie-wraps to obtain 0.50-inch minimum clearance.

(2) If damage and/or inadequate clearance is found: Repair damaged wires, replace damaged wires with new wires, and/or secure the wires using tie-wraps to obtain 0.50-inch minimum clearance.

(h) An inspection and corrective actions are also acceptable for compliance with the requirements of paragraphs (f) and (g) of this AD, if done as specified in paragraph (h)(1) or (h)(2) of this AD, as applicable.

(1) Boeing Alert Service Bulletin MD90–24A074, dated May 14, 2001, done before April 4, 2003.

(2) Boeing Alert Service Bulletin MD90–24A074, Revision 01, dated August 8, 2001, done before the effective date of this AD.

Alternative Methods of Compliance (AMOCs)

(i) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(j) You must use Boeing Alert Service Bulletin MD90–24A074, excluding Appendix, Revision 02, dated June 3, 2003, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846; Attention: Data and Service Management, Dept. C1–L5A (D800–0024). You can review copies at the Docket Management Facility office, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on January 26, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–1931 Filed 2–3–05; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1 and 155

RIN 3038–AC16

Distribution of ''Risk Disclosure Statement'' by Futures Commission Merchants and Introducing Brokers

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is amending Rule 1.55 to provide that non-institutional customers may indicate with a single signature, in addition to the acknowledgment of receipt of various disclosures and the making of certain elections, the consent referenced in Rules 155.3(b)(2) and 155.4(b)(2) and 155.4(b)(2) concerning customer permission for futures commission merchants (''FCMs'') and introducing brokers (''IBs'') to take the opposite side of an order. The Commission is also amending Rule 1.55(f) to specify that the acknowledgments required by Rules 155.3(b)(2) and 155.4(b)(2) are not required of institutional customers when they open an account.

DATES: Effective March 7, 2005.

FOR FURTHER INFORMATION CONTACT: Lawrence B. Patent, Deputy Director, or Susan A. Elliott, Special Counsel, Compliance and Registration Section, Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission. Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone: (202) 418–5439 or (202) 418–5464, or electronic mail: *lpatent@cftc.gov* or *selliott@cftc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 9, 2004 (69 FR 64873), the commission published a proposed amendment to Rule 1.55 to provide that the single signature by which non-institutional customers acknowledge receipt of basic risk disclosures of futures and option trading, and elect how hedging positions shall be handled in the event of a commodity broker bankruptcy, may also reflect the consent referenced in Rules 155.3(b)(2) and 155.4(b)(2) concerning customer permission for FCMs and IBs to take the opposite side of an order. The Commission adopted a similar rule amendment in November 2000,[1] but withdrew it the following month upon passage of the Commodity Futures Modernization Act of 2000.[2] Most of the rules adopted and withdrawn in 2000 were reproposed and re-adopted in 2001,[3] but this one was not. Because Commission staff received an inquiry about this issue, the Commission reproposed the rule amendment and sought comments.

II. Rule Amendments

Three comments were received, from the National Futures Association (''NFA''), the Futures Industry Association (''FIA'') and an FCM, Goldman Sachs & Co. All comments supported adoption of the proposed amendment to Rule 1.55(d)(1). In addition, the three commenters were unanimous in their recommendation that the Commission adopt another rule amendment that clarifies, in Rule 1.55(f), that acknowledgment to consent for an FCM or IB to take the opposite side of an order is not required of institutional customers when they open an account.

The commenters requested that Rule 1.55(f) also be amended to add the consent required under Commission Rules 115.3(b)(2) and 155.4(b)(2) to the prescribed disclosures, consents and elections that institutional customers are not required to acknowledge in opening an account with an FCM. The Commission believes that such a further amendment is consistent with the proposal and with the general structure of Rule 1.55 and that it is appropriate to clarify Rule 1.55(f) as the commenters suggest. The Commission emphasizes the point by cross-referencing Rule 1.55 in Rules 1.55.3 and 155.4.[4]

As the Commission emphasized in its proposal, the single signature acknowledgment format was first adopted in 1993 based on a rationale of customer sophistication. If, with the Commission's proposed rule amendment, non-institutional customers are now deemed sufficiently sophisticated to have their consents acknowledged with a single signature, it is certainly appropriate to assume that more sophisticated institutional customers understand that they are consenting to the trade practices described in Rule 155.3(b)(2) and 155.4(b)(2) without a separate acknowledgment when an account is opened.

Section 4b of the Act[5] nonetheless requires intermediaries to have the prior consent of the customer before knowingly taking, directly or indirectly, the opposite side of a customer's order. Thus, as one of the commenters pointed out, it is still the responsibility of the entity opening the account to ensure that prospective customers give ''the consent required under this rule,'' even when the customer is an institutional customer.[6] The amendment of Rule 1.55(f) permits an entity to choose the most appropriate means to accomplish that objective. Finally, Rules 155.3(b)(2) and 155.4(b)(2) are amended to cross-reference Rule 1.55(d)(1).

[1] 65 FR 77993 at 78013 (December 13, 2000).

[2] 65 FR 82272 (December 28, 2000).

[3] 66 FR 45221 at 45226 (August 28, 2001) (proposed rules) and 66 FR 53510 at 53513 (October 23, 2001) (final rules).

[4] The Commission took a similar approach when it amended Rule 1.55 as well as Rule 1.33 concerning electronic transmission of customer account statements. *See* 66 FR 53517 (Oct. 23, 2001).

[5] Commodity Exchange Act § 4b(a)(2)(iv) (''unlawful * * * to fill such order by offset against the order or orders of any other person, or willfully and knowingly and without the prior consent of such person to become the buyer in respect to any selling order of such person, or become the seller in respect to any buying order of such person''), 7 U.S.C. 4b(2)(C)(iv) (2003).

[6] Comment letter of Goldman Sachs & Co., December 9, 2004 at p. 2.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–611, requires that agencies, in proposing rules, consider the impact of those rules on small business. The Commission has previously established certain definitions of ''small entities'' to be used by the Commission in evaluating the impact of its rules on such entities in accordance with the RFA.[7] The Commission previously has determined that, based upon the fiduciary nature of the FCM/customer relationships, as well as the requirement that FCMs meet minimum financial requirements. FCMs should be excluded from the definition of small entities. With respect to IBs, the CFTC has stated that it is appropriate to evaluate within the context of a particular rule proposal whether some or all of the affected entities should be considered small entities and, if so, to analyze the economic impact on them of any rule.[8] In the regard, the amendment to Rule 1.55(d)(1) adopted herein does not require any IB to change its current method of doing business, and in fact eases a regulatory burden by permitting a single signature of the customer to represent an additional consent required by Commission regulations. The amendments to Rules 1.55(f) and 155.3(b)(2) and 155.4(b)(2) clarify existing rules. No comments were received on this issue.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 [9] imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the Paperwork Reduction Act (''PRA''). The amendments to Rules 1.55(d) and 155(f) that are the subject of this rulemaking do not alter the paperwork burden associated with the OMB Collection of Information submission, OMB Control Number 3038–0022, Rules Pertaining to Contract Markets and Their Members, where the Commission most recently described the paperwork burden associated with the 2001 rulemaking amendments.[10] Thus, there is no need for an additional submission pursuant to the PRA.

[7] 47 FR 18618–18621 (April 30, 1982).

[8] Id.

[9] Pub. L. 104–13 (May 13, 1995).

[10] *See* 66 FR 45221, 45228 (August 28, 2001).

List of Subjects

17 CFR Part 1

Brokers, Commodity futures, Consumer protection, Disclosure, Reporting and recordkeeping requirements.

17 CFR Part 155

Brokers, Commodity futures, Reporting and recordkeeping requirements.

■ In consideration of the foregoing, and pursuant to the authority contained in the Commodity Exchange Act and, in particular, Sections 4b, 4c(b), and 8a(5) thereof, 7 U.S.C. 6b, 6c(b), and 12a(5) (2000), and pursuant to the authority contained in 5 U.S.C. 552 and 552b (2003), the Commission hereby amends Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 1a, 2, 4, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 6p, 7, 7a, 7b, 8, 9, 12, 12a, 12c, 13a, 13a–1, 16, 16a, 19, 21, 23, and 24, as amended by the Commodity Futures Modernization Act of 2000, appendix E of Pub. L. 106–554, 114 Stat. 2763 (2000).

■ 2. Section 1.55 is amended by revising paragraphs (d)(1) and (f) to read as follows:

§ 1.55 Distribution of ''Risk Disclosure Statement'' by futures commission merchants and introducing brokers.

* * * * *

(d) * * *

(1) Prior to the opening of such account, the futures commission merchant or introducing broker obtains an acknowledgement from the customer, which may consist of a single signature at the end of the futures commission merchant's or introducing broker's customer account agreement, or on a separate page, of the disclosure statements, consents and elections specified in this section and § 1.33(g), and in §§ 33.7, § 155.3(b)(2), § 155.4(b)(2), and § 190.06 of this chapter, and which may include authorization for the transfer of funds from a segregated customer account to another account of such customer, as listed directly above the signature line, provided the customer has acknowledged by check or other indication next to a description of each specified disclosure statement, consent or election that the customer has received and understood such disclosure statement or made such consent or election; and

* * *

(f) A futures commission merchant or, in the case of an introduced account, an introducing broker, may open a commodity futures account for an ''institutional customer'' as defined in § 1.3(b) without furnishing such institutional customer the disclosure statements or obtaining the acknowledgments required under paragraph (a) of this section, §§ 1.33(g) and 1.65(a)(3), and §§ 30.6(a), 33.7(a), 155.3(b)(2), 155.4(b)(2) and 190.10(c) of this chapter.

* * * * *

PART 155—TRADING STANDARDS

■ 3. The authority citation for part 155 continues to read as follows:

Authority: U.S.C. 6b, 6c, 6g, 6j and 12a, unless otherwise noted.

■ 4. Section 155.3 is amended by revising paragraph (b)(2) as follows:

§ 155.3 Trading standards for futures commission merchants.

* * * * *

(b) * * *

(2)(i) Knowingly take, directly or indirectly, the other side of any order of another person revealed to the futures commission merchant or any of its affiliated persons by reason of their relationship to such other person, except with such other person's prior consent and in conformity with contract market rules approved by or certified to the Commission.

(ii) In the case of a customer who does not qualify as an ''institutional customer'' as defined in § 1.3(g) of this chapter, a futures commission merchant must obtain the customer's prior consent through a signed acknowledgment, which may be accomplished in accordance with § 1.55(d) of this chapter.

* * * * *

■ 5. Section 155.4 is amended by revising paragraph (b)(2) as follows:

§ 155.4 Trading standards for introducing brokers.

* * * * *

(b) * * *

(2)(i) Knowingly take, directly or indirectly, the other side of any order of another person revealed to the introducing broker or any of its affiliated persons by reason of their relationship to such other person, except with such other persons's prior consent and in conformity with contract market rules approved by or certified to the Commission.

(ii) In the case of a customer who does not qualify as an ''institutional customer'' as defined in § 1.3(g) of this chapter, an introducing broker must obtain the customer's prior consent through a signed acknowledgment, which may be accomplished in accordance with § 1.55(d) of this chapter.

* * * * *

Dated: January 27, 2005.

By the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 05–1906 Filed 2–3–05; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1310 and 1313

[Docket No. DEA–137N]

RIN 1117–AA31

Chemical Mixtures; Temporary Waiver of Import/Export Requirements

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Temporary waiver of import/export requirements.

SUMMARY: On December 15, 2004, the Drug Enforcement Administration (DEA) published a final rule that implemented regulations pertaining to chemical mixtures that contain any of 27 listed chemicals regulated under the Controlled Substances Act (21 U.S.C. 801 *et seq.*). That rulemaking became effective on January 14, 2005.

Following publication of the final rule, certain segments of the chemical industry expressed concerns to DEA regarding difficulty in fully complying with DEA import/export notification requirements as specified in 21 CFR part 1313 by this deadline. Therefore, in order to avoid interruption of legitimate import/export distributions, DEA is providing a waiver of the import/export reporting requirements as specified in 21 CFR part 1313 until May 14, 2005. As such, regulated persons will temporarily not be required to submit advance notification for import, export and transshipment transactions for chemical mixtures regulated solely due to the presence of these 27 listed chemicals until May 14, 2005. This temporary waiver applies only to import, export and transshipment notification requirements; all other chemical control requirements set forth in the final rulemaking published on December 15, 2004, shall remain in full force and effect.

DATES: Effective February 4, 2005. The new deadline for providing import, export and transshipment notification for regulated chemical mixtures containing these 27 listed chemicals will be May 14, 2005.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug & Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–7183

SUPPLEMENTARY INFORMATION: On December 15, 2004, the Drug Enforcement Administration (DEA) published a final rule (69 FR 74957) that implemented regulations pertaining to chemical mixtures that contain any of 27 listed chemicals regulated under the Controlled Substances Act (CSA). That rulemaking became effective on January 14, 2005.

Following publication of the final rule concerns were raised by various segments of the chemical industry regarding their difficulty in fully complying with DEA import/export notification requirements as specified in 21 CFR part 1313 by this deadline. DEA received correspondence from two national chemical associations and from one major chemical producer. Additionally, DEA received verbal communication from industry that expressed concerns regarding the large number of potentially affected mixtures and the difficulty industry was having in meeting deadlines for submitting import/export notification. After carefully considering the concerns expressed by industry, DEA has decided to postpone the implementation of the import/export notification requirements as specified in 21 CFR part 1313 until May 14, 2005. This temporary waiver shall apply only to chemical mixtures which became regulated under the December 15, 2004 final rule (69 FR 74957).

While the submission of import, export and transshipment information to DEA is an important provision in countering the potential diversion of these materials, this temporary waiver is being provided to allow industry ample time to ensure their full compliance with CSA import/export regulatory requirements as specified in 21 CFR part 1313. As such, DEA will be temporarily waiving the requirement for regulated persons to submit advance notification for import, export and transshipment transactions for chemical mixtures which are regulated solely due to the presence of the 27 listed chemicals which were the subject of the December 15, 2004 final rule. This temporary waiver applies only to import, export and transshipment notification requirements. All other chemical control requirements set forth in the final rulemaking published on December 15, 2004 (69 FR 74957) shall remain in full force and effect.

The new deadline for providing import, export and transshipment notification for regulated chemical mixtures containing these 27 listed chemicals will be May 14, 2005.

Provisions of December 15, 2004 Final Rule (69 FR 74957) Which Do Not Change

For any person distributing, importing, or exporting any amount of a regulated mixture containing a List I chemical, the CSA requires that person to obtain a DEA registration. DEA recognizes that it is not possible for persons who are subject to the registration requirement to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, in order to allow continued legitimate commerce in regulated mixtures, the December 15, 2004 final rule established a temporary exemption from the registration requirement (in 21 CFR 1310.09) for persons desiring to engage in activities with regulated mixtures that are subject to registration requirements, provided that DEA receives a properly completed application for registration or an application for exemption (pursuant to 21 CFR 1310.13) for their chemical mixture(s) on or before February 14, 2005. The temporary exemption from registration for such persons will remain in effect until DEA takes final action on their application(s).

Any person whose application for exemption is subsequently rejected by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, if DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The deadline for submission of an application for registration, or an application for exemption, remains February 14, 2005 in order to obtain the temporary exemption from registration.

None of the temporary exemptions discussed in this rulemaking suspend applicable federal criminal laws relating to the regulated mixtures, nor does it supersede state or local laws or regulations. All handlers of a regulated

mixture must comply with applicable state and local requirements in addition to the CSA regulatory controls.

Dated: January 28, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 05–2212 Filed 2–3–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AK94

Payment for Non-VA Physician and Other Health Care Professional Services Associated With Either Outpatient or Inpatient Care Provided at Non-VA Facilities

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Veterans Affairs (VA) medical regulations concerning payment for non-VA health care professional services that are associated with either outpatient or inpatient care provided to eligible VA beneficiaries at non-VA facilities. Currently, the medical regulations require all VA facilities to reimburse for non-VA health care professional services based upon the Centers for Medicare and Medicaid Services (CMS) physician fee schedule in effect at the time the services are provided. However, if the standard payment methodology is implemented in Alaska, VA payments will be significantly less than the usual and customary charges for the state. This may limit VA patient access to non-VA health care. Since a large portion of VA health care provided in Alaska is obtained from non-VA sources, this could negatively impact the quality of care provided veterans living in that state. This rule establishes an Alaska-specific payment methodology for inpatient and outpatient non-VA health care professional services within that state. The rule ensures that amounts paid to health care providers represent the local cost to furnish a service, while continuing to achieve program cost reductions.

DATES: *Effective Date:* This rule shall become effective on March 7, 2005.

Applicability Date: This rule shall be applicable to all claims for payment for services rendered on or after April 1, 2005.

FOR FURTHER INFORMATION CONTACT: Susan Schmetzer, Chief, Policy & Compliance Division, Health Administration Center, Department of Veterans Affairs, P.O. Box 65020, Denver, CO 80206, telephone 303–331–7552. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on July 29, 2003 (68 FR 44507) we proposed to amend VA's medical regulations at 38 CFR part 17 to provide for the payment of non-VA physician services in Alaska that are associated with either outpatient or inpatient care provided to eligible VA beneficiaries at non-VA facilities. We provided a 60-day comment period that ended on September 29, 2003. We received one comment, in which the commenter suggested that VA adopt the Official Alaska Workers' Compensation Medical Fee Schedule as a basis for such payments. No changes are made based on this comment, as adoption of the Official Alaska Workers' Compensation Medical Fee Schedule would not achieve the dual goal of ensuring that the amounts paid to health care providers better represent the local cost to furnish a service, while continuing to achieve program cost reductions.

A number of technical changes of a non-substantive nature have been made in this final rule. The proposed rule described the title of this rule as *Payment for Non-VA Physician Services Associated with Either Outpatient or Inpatient Care Provided at Non-VA Facilities.* The use of the phrase ''non-VA physician,'' both in the title of 38 CFR 17.56 and throughout the regulation, is imprecise, as the rule applies to all non-VA physician and other health care professional services associated with outpatient or inpatient care provided at non-VA facilities. In order to reconcile the terminology used in this rule with common practice in VA, the phrase ''non-VA physician'' will be replaced with ''non-VA health care professional services.'' Additionally, the language was clarified to state the rates payable are based on the geographic location of where the services were rendered.

The proposed rule stated that VA would rely on Current Procedural Terminology (CPT) codes utilized by Centers for Medicare and Medicaid Services (CMS) to pay for these non-VA services. The reference to CPT codes was too restrictive, as CMS uses other national coding sets for health care professional services. Therefore, the references to CPT codes were removed. The final rule refers generally to the use of national standard code sets.

The proposed rule referenced Fiscal Year (FY) 2002 as the base year for determining various costs. In light of the passage of time since publication of the proposed rule, and in order to reflect the most up-to-date data, this reference has been changed to FY 2003 throughout the final rule.

The proposed rule stated that for services that VA did not have occasion to pay for in Alaska in FY 2002, and for services represented by CPT codes established after FY 2002, VA will take the Centers for Medicare and Medicaid Services' rate for each unpaid code and multiply it times the average percentage paid by VA in Alaska for Centers for Medicare and Medicaid Services-like codes. Applying this rule only to services that VA had no occasion to pay during the previous Fiscal Year was unnecessarily narrow and would limit VA's ability to accurately gauge a reasonable payment. It is also inconsistent with other provisions of this rule, which require a minimum of eight occurrences. Therefore, the final rule has been revised to apply this rule to services that VA provided *less than eight times* in Alaska during the previous Fiscal Year. Clarification was also made that this rule would be applicable to unit-based codes as the VA moved from a single payment per code irrespective of units to unit-based payment in FY 2004, and development of a fee schedule that is not unit-based would be inconsistent and inaccurate.

The proposed rule stated that VA would increase the amounts on the VA Fee Schedule for Alaska annually in accordance with annual inflation rate adjustments published by CMS. The VA will use the national Medicare Economic Index (MEI) for that purpose. The MEI measures inflation in physician practice cost and general wage levels. The VA will not make modifications to the MEI based on regional factors because doing so would not achieve the dual goal of ensuring that the amounts paid to health care providers represent the local cost to furnish a service, while continuing to achieve program cost reductions.

Administrative Procedure Act

The modifications in this final rule are logical and reasonable outgrowths of the proposed changes set forth in the proposed rule and are intended to clarify the intent of the proposed rule. Based on the rationales set forth in the proposed rule and those contained in this document, we are adopting the provisions of the proposed rule as a final rule with the modifications described above.

Unfunded Mandates

The Unfunded Mandates Reform Act requires, in 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any given year. This final rule would have no such effect on State, local, or tribal governments, or the private sector.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Executive Order 12866

The Office of Management and Budget has reviewed this document under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601 through 612. The final rule would not cause a significant economic impact on health care providers, suppliers, or entities since only a small portion of the business of such entities concerns VA beneficiaries. Therefore, pursuant to 5 U.S.C. 605(b), the final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance Numbers are 64.009, 64.010 and 64.011.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Government programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing home care, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: October 20, 2004.

Anthony J. Principi,

Secretary of Veterans Affairs.

■ For the reasons set out in the preamble, 38 CFR part 17 is amended as set forth below:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

■ 2. Section 17.56 is amended by:
■ a. Revising the section heading.
■ b. In paragraph (a), removing ''Except for anesthesia services,'' and adding, in its place, ''Except for anesthesia services, and services provided in the State of Alaska under paragraph (d) of this section,''; removing ''Department of Health & Human Services, Health Care Financing Administration (HCFA) under Medicare's participating'' and adding, in its place, ''Centers for Medicare and Medicaid Services' (CMS) participating''; removing ''calculated under Medicare's participating'' and adding, in its place, ''calculated under Centers for Medicare and Medicaid Services' participating''; and removing all references to ''non-VA physician services'' and adding, in their place, ''non-VA health care professional services''.
■ c. In paragraph (b), removing ''Medicare's participating'' and adding, in its place, ''Centers for Medicare and Medicaid Services' participating''; and removing ''calculating the Medicare fee'' and adding, in its place, ''calculating the Centers for Medicare and Medicaid Services' fee''.
■ d. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively.
■ e. Adding a new paragraph (d).
■ f. In redesignated paragraph (f), removing the phrase ''paragraphs (a) through (d)'' and adding, in its place, ''paragraphs (a) through (e)''.

The revision and addition read as follows:

§ 17.56 Payment for non-VA physician and other health care professional services.

* * * * *

(d) For services rendered in Alaska, VA will pay for services in accordance with a fee schedule that uses the Health Insurance Portability and Accountability Act mandated national standard coding sets. VA will pay a specific amount for each service for which there is a corresponding code. Under the VA Alaska Fee Schedule the amount paid in Alaska for each code will be 90 percent of the average amount VA actually paid in Alaska for the same services in Fiscal Year (FY) 2003. For services that VA provided less than eight times in Alaska in FY 2003, for services represented by codes established after FY 2003, and for unit-based codes prior to FY 2004, VA will take the Centers for Medicare and Medicaid Services' rate for each code and multiply it times the average percentage paid by VA in Alaska for Centers for Medicare and Medicaid Services-like codes. VA will increase the amounts on the VA Alaska Fee Schedule annually beginning in 2005 in accordance with the published national Medicare Economic Index (MEI). For those years where the annual average is a negative percentage, the fee schedule will remain the same as the previous year. Payment for non-VA health care professional services in Alaska shall be the lesser of the amount billed, or the amount calculated under this subpart.

* * * * *

(Authority: 38 U.S.C. 513, 1703, 1728)

[FR Doc. 05–2107 Filed 2–3–05; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R04–OAR–2004–KY–0001–200425(w); FRL–7868–8]

Approval and Promulgation of Implementation Plans for Kentucky: 1-Hour Ozone Maintenance Plan Update for Edmonson Area; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to adverse comment, EPA is withdrawing the direct final rule published December 17, 2004, (69 FR 75473) approving revisions to the Edmonson County portion of the State Implementation Plan (SIP) submitted by the Commonwealth of Kentucky on August 24, 2004. The submittal provides the 10-year update to the original 1-hour ozone maintenance plans for three 1-hour ozone maintenance areas, including the Edmonson County Maintenance Area, and also provides revised 2004 motor vehicle emission budgets (MVEBs) and establishes 2015 MVEBs. EPA stated in the direct final rule that if EPA received adverse comment by January 18, 2005, the rule would be withdrawn and not take effect. EPA subsequently received adverse comment. EPA will address the comment in a subsequent final action based upon the proposed action also

published on December 17, 2004 (69 FR 75495). EPA will not institute a second comment period on this action.

DATES: The direct final rule is withdrawn as of February 4, 2005.

FOR FURTHER INFORMATION CONTACT: Michele Notarianni, Air Planning Branch, U.S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. ((404) 562–9031 (phone) or *notarianni.michele@epa.gov* (e-mail).)

List of Subjects in 40 CFR Part 52

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

Dated: January 24, 2005.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 05–2069 Filed 2–3–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FL–87; FL–89–200501, FRL–7869–2]

Approval and Promulgation of Implementation Plans; Florida: Citrus Juice Processing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final conditional approval.

SUMMARY: The EPA is conditionally approving a revision to the Florida State Implementation Plan (SIP) consisting of a new Florida statute and implementing regulations that set emission limits for existing and new equipment at existing citrus juice processing facilities in Florida. This approval is conditioned upon a commitment from the State to adopt specific enforceable measures, as stated in the proposed rule published January 30, 2004 (69 FR 4459), within one year from the effective date of this rule. If the State fails to meet its commitment by adopting and submitting to EPA the necessary revisions within the one-year period, the approval is treated as a disapproval.

DATES: *Effective Date:* This rule will be effective March 7, 2005.

ADDRESSES: EPA has established a docket for this action under Docket Control No. FL–87 and FL–89. Some information may not be publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available at the Air Permits Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays. Copies of the State submittal are also available for public inspection during normal business hours, by appointment at the State Air Agency: Florida Department of Environmental Protection, Division of Air Resources Management, 2600 Blair Stone Road, Tallahassee, Florida 32399–2400.

FOR FURTHER INFORMATION CONTACT: Ms. Kelly Fortin, Air Permits Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9117. Ms. Fortin can also be reached via electronic mail at *fortin.kelly@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Today's Action

Today's action is a conditional approval under section 110(k)(4) of the Clean Air Act (CAA). EPA may conditionally approve a plan based on a commitment from the State to adopt specific enforceable measures within one year from the effective date of final conditional approval. Because the revisions would materially alter the existing SIP approved rule, the State must make a SIP submittal. If the State fails to adopt and submit the specified measures by the end of one year from the effective date of this conditional approval, or fails to make a submittal, EPA will issue a finding of disapproval. If EPA determines that the rule with the specified measures is approvable, EPA will propose approval of the rule in the **Federal Register**. EPA will conditionally approve a certain rule only once.

II. Background

EPA is taking this action in response to a request from the Florida Department of Environmental Protection (FDEP) to revise Florida's SIP and Title V operating permit program to include an alternative regulatory program for citrus juice processing facilities. FDEP's complete submittal, received by EPA on July 29, 2002, includes a new citrus statute (Florida Statute 403.08725), which the State adopted in July 2000 and amended on June 12, 2003, as well as draft implementing regulations and supporting material. FDEP formally adopted these implementing regulations in December 2002. 62–210.340 F.A.C. FDEP also requested that the statute and regulation be considered by EPA pursuant to the Joint EPA/State Agreement to Pursue Regulatory Innovation between EPA and the Environmental Council of the States (''ECOS''). 63 FR 24784. After a detailed review, EPA responded to FDEP with letters, dated September 18, 2002, and April 24, 2003, listing several changes to the program that must be made in order for EPA to incorporate the program into the Florida SIP. On January 31, 2003, FDEP made a supplemental submittal outlining their intent to make necessary statutory and regulatory revisions to the program. In a **Federal Register** notice published on January 30, 2004, EPA requested comment on a proposal to conditionally approve the proposed changes to the Florida SIP. The **Federal Register** notice described the proposed program and identified specific deficiencies that EPA has determined must be corrected in order for EPA to approve the program as part of the Florida SIP. You may access this notice and the January 30, 2004 **Federal Register** document electronically at *http://www.regulations.gov.* No comments were received by EPA during the 30 day public comment period.

The proposed program requires the existing juice processing facilities in Florida to comply with specified terms in the statute when they construct, operate, and modify air emissions units. For some units these conditions are different from those required by the conventional construction and operating permit requirements required by the SIP-approved Florida regulations that currently apply to citrus juice processing facilities. The statute requires a 65 percent recovery (50 percent the first year) of d-limonene oil from peel processed through the peel dryer. This reduction will decrease emissions of volatile organic compounds (VOC) from these facilities by approximately 38 percent. The citrus facilities can comply with the VOC emission limitations through a combination of emission controls, pollution prevention, and emission credits that can be generated through over-control of the juice processing facilities. The statute includes requirements for emissions of VOC, nitrogen oxides (NO_X), sulfur dioxide (SO_2), and particulate matter (PM), for existing units and for new units. New

units include units that are modified or are relocated. The program also incorporates all applicable federal standards (such as maximum achievable control technology (MACT) for hazardous air pollutants and New Source Performance Standards (NSPS)). The statute and implementing regulations will be considered a general permit for the purpose of Title V of the CAA. Further details regarding the program can be found in EPA's January 30, 2004 **Federal Register** notice and in the public docket referenced above.

Today's approval is conditioned upon FDEP making specific changes to the State statute and regulations. FDEP will have one year from the effective date of this conditional approval to complete and submit to EPA the necessary program revisions. After EPA receives the State's submittal, EPA will review the changes to ensure that they remedy the deficiencies identified in the January 30, 2004 notice. These deficiencies relate to: the allowable fuel sulfur content; PM–10 emissions; a maximum production limit; regulated and toxic air pollutants; public petitions and judicial review; performance measures; and program review. If EPA believes these changes are approvable, EPA will publish a proposed action to approve the SIP and Title V revisions, again soliciting public comment. The Florida statute previously provided that it would expire if EPA did not approve the program as revisions to Florida's SIP and Title V program by January 31, 2005, and that in that event, the applicable requirements would revert back to those of the conventional permitting programs. However, the statutory ''sunset'' date has been extended to July 1, 2005 (F.S. 403.08725, as amended 5/28/04).

III. Final Action

EPA is conditionally approving the Florida SIP revision consisting of an innovative strategy to create an alternative program for regulating the existing citrus juice industry, which was submitted on January 30, 2001, with additional material submitted on July 16, 2002 and January 31, 2003, with the condition that Florida correct the deficiencies described in our January 30, 2004 action (69 FR 4459). EPA is taking this action pursuant to our authority in section 110(k)4 of the CAA.

IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves State law as meeting Federal requirements and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. 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 rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 5, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: January 25, 2005.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

■ Part 52 of chapter I, title 40, *Code of Federal Regulations,* is amended as follows:

PART 52—[AMENDED]

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

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

Subpart (K)—Florida

■ 2. A new § 52.519 is added to read as follows:

§ 52.519 Identification of plan-conditional approval.

EPA is conditionally approving a revision to the Florida State Implementation Plan (SIP) consisting of a new citrus statute (Florida Statute 403.08725), as well as implementing regulations (62–210.340 F.A.C.) based upon a commitment from the State to adopt specific enforceable measures by March 7, 2006. If the State fails to meet its commitment by March 7, 2006, the approval is treated as a disapproval.

[FR Doc. 05–2072 Filed 2–3–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7868–6]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule of deletion of the Southern Maryland Wood Treating Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region III is publishing a direct final rule of deletion of the Southern Maryland Wood Treating Superfund Site (Site), located in Hollywood (St. Mary's County), Maryland, from the National Priorities List (NPL).

The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), is Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final rule of deletion is being published by EPA with the concurrence of the State of Maryland, through the Maryland Department of the Environment (MDE), because EPA has determined that all appropriate response actions under CERCLA have been completed and, therefore, further remedial action pursuant to CERCLA is not appropriate.

DATES: This direct final rule deletion will be effective April 5, 2005, unless EPA receives adverse comments by March 7, 2005. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Comments may be mailed to: Robert Sanchez, Remedial Project Manager, U.S. EPA Region III (3HS23), 1650 Arch Street, Philadelphia, PA 19103–2029, (215) 814–3451.

Information Repositories: Comprehensive information about the Site is available for viewing and copying at the Site information repositories located at: U.S. EPA Region III, Regional Center for Environmental Information (RCEI), 1650 Arch Street (2nd Floor), Philadelphia, PA 19103–2029, (215) 814–5254, Monday through Friday, 8 a.m. to 5 p.m.; and in Maryland at the St. Mary's County Library, 23250 Hollywood Road, Leonardtown, MD 20650 (301) 475–2846, Monday through Friday, 8 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Robert Sanchez, Remedial Project Manager, U.S. EPA Region III (3HS23), 1650 Arch Street, Philadelphia, PA 19103–2029, (215) 814–3451 or 1–800–553–2509.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Site Deletion
V. Deletion Action

I. Introduction

EPA Region III is publishing this direct final notice of deletion of the Southern Maryland Wood Treating Superfund Site from the NPL.

The EPA identifies sites that appear to present a significant risk to public health or the environment and maintains the NPL as the list of those sites. As described in § 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions if conditions at a deleted site warrant such action.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective April 5, 2005, unless EPA receives adverse comments by March 7, 2005, on this document or the parallel notice of intent to delete published in the ''Proposed Rules'' section of today's **Federal Register**. If adverse comments are received within the 30-day public comment period on this notice or the notice of intent to delete, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Southern Maryland Wood Treating Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that releases may be deleted from the NPL where no further response is appropriate. In making a determination to delete a Site from the NPL, EPA shall consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. All appropriate Fund-financed (Hazardous Substance Superfund Response Trust Fund) response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Even if a site is deleted from the NPL, where hazardous substances, pollutants, or contaminants remain at the deleted site above levels that allow for unlimited use and unrestricted exposure, CERCLA section 121(c), 42 U.S.C. 9621(c), requires that a subsequent review of the site be conducted at least every five years after the initiation of the remedial action at the deleted site to ensure that the action remains protective of public health and the environment. If new information becomes available which indicates a need for further action, EPA may initiate remedial actions. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

(1) EPA consulted with the State of Maryland on the deletion of the Site from the NPL prior to developing this direct final notice of deletion.

(2) The State of Maryland has concurred with deletion of the Site from the NPL.

(3) Concurrently with the publication of this direct final notice of deletion, a notice of the availability of the parallel notice of intent to delete published today in the ''Proposed Rules'' section of the **Federal Register** is being published in a major local newspaper of general circulation at or near the Site and is being distributed to appropriate Federal, State, and local government officials and other interested parties; the newspaper notice announces the 30-day public comment period concerning the notice of intent to delete the Site from the NPL.

(4) EPA placed copies of documents supporting the deletion in the Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this notice or the companion notice of intent to delete also published in today's **Federal Register**, EPA will publish a timely notice of withdrawal of this direct final notice of deletion before its effective date. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the Site from the NPL:

Site History and Characteristics

Land and Resource Use

The Southern Maryland Wood Treating Site is approximately 25 acres in size and is located on a 94-acre parcel of land just west of Maryland Route 235 approximately one mile north of Hollywood, Maryland. The upland portion of the Site where most of the remedial work took place is approximately 25 acres. The remainder of the Site is situated in or near a flood plain area. Title of the property which constitutes the Site is being held by a bankruptcy trustee. The Site is bounded by residential, agricultural and wooded tracts of land. The Site is the head waters of Old Tom's Run which eventually flows into Breton Bay and then into the Potomac River.

History of Contamination/Response Actions

The Site was owned and operated by the Southern Maryland Wood Treating Corporation from 1965 to 1978 as a pressure treatment wood preservation facility. Creosote and pentachlorophenol (PCP) were used as wood preservatives by the facility. Six unlined lagoons were used for disposal of liquid wastes from the process. As a result of such disposal practices, onsite soils and ground water beneath the lagoons became contaminated. Non-aqueous phase liquids (NAPLs), both light (LNAPLs) and dense (DNAPLs), were found in the subsurface beneath the lagoons and above the underlying clay layer. Additionally, due to ground water discharge to the onsite pond from the lagoon area, surface water and sediments in the onsite pond and sediments in Old Tom's Run (east and west tributaries) became contaminated. Storage of treated wood onsite resulted in surface soil contamination in the northern section of the site and northeast tank area.

On March 14, 1985, EPA initiated its first response action, namely a removal action, at the Site after the discovery of contaminated material seeping into the onsite freshwater pond. During the removal action EPA excavated 1,400 cubic yards of contaminated sediments from the freshwater pond. The sediments were stabilized with cement kiln dust and encapsulated on the Site, and remained on the Site until a final treatment. The Site was promulgated on the National Priorities List on June 10, 1986. In 1988, EPA concluded a Remedial Investigation (RI) and Feasibility Study (FS) for the Site. Based on the findings of these studies, EPA issued a Record of Decision on June 29, 1988 (1988 ROD). In the 1988 ROD EPA's selected remedy consisted of the construction of a subsurface barrier wall around the former lagoon area, excavation and onsite incineration of contaminated soil and pumping and treatment of contaminated ground water. Construction of the substance barrier (sheet pile wall) was completed in November of 1990. By May 1992, design of the incinerator and the ground water treatment system were 95% complete. At that point, local citizens and local government entities expressed opposition to an onsite incinerator. The design work was suspended and EPA proposed to conduct a Focused Feasibility Study (FFS) to reevaluate the remedy for the Site.

On June 29, 1993, a second removal action was initiated to address certain immediate threats at the Site while the FFS was being conducted. This action included the demolition of several buildings that were in danger of collapse; the removal and off-site disposal of liquid and solid waste in numerous tanks and retorts; maintaining the pile of previously excavated and stabilized sediment; the construction of an underflow dam to reduce the amount of contaminated material migrating from the onsite pond into the west tributary stream; the construction of a trench upgradient of the pond to collect contaminated ground water, and the construction of a water treatment facility. The water treatment plant (WTP–1) became fully operational in 1995.

The Focused Feasibility Study (FFS) was completed in February 1995. Based on the FFS, the EPA issued a second Record of Decision on September 8, 1995 (1995 ROD). In this 1995 ROD, EPA revised the remedy selected in the 1988 ROD from incineration to thermal desorption which the community accepted as the remedy. In addition to excavation of the upland area, some excavation in the small tributary stream that receives storm water runoff from the former lagoon area was conducted.

Two large continuous thermal desorption units with vapor recovery units were constructed on-site and became operational in June 1998. Soil treatment operations continued until October 6, 2000. At that point, approximately 270,600 tons of contaminated soils and sediments had been successfully treated. The Site was re-graded and re-vegetated with a diverse mixture of wildflowers and grains suitable for wildlife habitant. Demobilization activities began in October 2000 and continued until December 2000.

Cleanup Standards

During the excavation and thermal desorption process, but before backfilling was conducted, all treated soil was sampled to determine if contaminants had been properly removed from the soils and sediments. Based on this sampling, EPA determined that all of the treated Site soils were cleaned to the required performance standards. These standards were established in the 1995 ROD as Remedial Action Objectives (''RAOs''). The RAOs set soil clean-up levels of 0.1 ppm Benzo (a) Pyrene (B(a)P) equivalent for surface soils (within two feet of the surface) and 1.0 ppm B(a)P equivalent

for subsurface soils (below two feet from the surface). However, during the remedial action data showed that in areas where the Site soils were below the Benzo (a) Pyrene (B(a)P) clean-up levels there were still high levels of pentachlorophenol (PCP) in the soil. To assure that the soil in these areas was treated, a non-significant change to the 1995 ROD was issued by EPA on March 5, 1999. This non-significant change established a cleanup level of 5.0 ppm PCP. In addition, another non-significant change was the use of treated soils from the Site as backfill below the water table. These treated soils were required to meet a clean-up level of 1.7 ppm PCP. This change from the 1995 ROD was announced during the public meeting on November 7, 1996 and documented in the ''Site Specific Work Plan,'' dated July 1997.

Post Closure Monitoring

A Post Closure Monitoring Plan, dated November 2000, was prepared to verify the success of the cleanup. The plan required sampling a network of monitoring wells throughout the Site including one well at the center of the former lagoon area. In addition the plan required the evaluation of the restored uplands and wetlands areas that had undergone excavation, backfilling, and re-vegetation. The monitoring wells were sampled quarterly from October 2000 to September 2002. Samples were analyzed for target compounds such as semi-volatiles, polynuclear aromatic hydrocarbons (PAH), and pentachlorophenol (PCP). All the sampling results showed that levels for these contaminants were well below their respective Maximum Contaminant Levels (MCLs) established under the Safe Drinking Water Act, 42 U.S.C. 300f *et seq.* Formal inspections of the wetland and upland areas were conducted concurrently with the monitoring well sampling effort. These areas showed no signs of erosion. All disturbed wetland areas have stabilized. The disturbed uplands areas are currently stabilized with grass, and the overall upland area is showing 95 percent total herbaceous coverage. After completion of sampling in September 2002 all monitoring wells and the 600-foot deep production well were subsequently closed out in accordance with MDE regulations for well abandonment. The production well required special close-out procedures involving blasting. The concern for this very deep well was that ground water from the upper non-potable aquifer could migrate down to the lower potable aquifer along possible voids on the outside of the well sleeve. Complete separation of these two aquifers was assured by blasting the well sleeve open at a point where there was an impervious clay layer between the upper and lower aquifers and then pumping in grout material to seal the well.

Five-Year Review

EPA has completed two Five-Year Reviews for this Site. The first was completed on September 30, 1994 and the second on September 30, 1999. Since the clean-up was ongoing these reviews were not required by statute, but were conducted as a matter of policy.

Five-Year Reviews are required at sites where the remedial action results in hazardous substances, pollutants or contaminants remain at the site above levels that allow for unrestricted use and unrestricted exposure. The response actions conducted at the Southern Maryland Wood Treating Site are now complete, and allow for unlimited use and unrestricted exposure, thus no additional Five-Year Reviews will be conducted for this Site.

Community Involvement

Public participation activities have been satisfied as required in CERCLA section 113(k), 42 U.S.C. 9613(k), and CERCLA section 117, 42 U.S.C. 9617. Documents in the Site docket which EPA relied on for recommendation of the deletion of the Site from the NPL are available to the public in the information repositories.

V. Deletion Action

EPA, with the concurrence of the State of Maryland, has determined that all appropriate responses under CERCLA have been completed at the Site, and that no further response actions are necessary. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective April 5, 2005, unless EPA receives adverse comments by March 7, 2005, on this notice or the parallel notice of intent to delete published in the ''Proposed Rules'' section of today's **Federal Register**. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and it will not take effect and EPA will also prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: January 26, 2005.

Richard J. Kampf,

Acting Regional Administrator, Region III.

■ For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

■ 2. Table 1 of Appendix B to Part 300 is amended under Maryland (''MD'') by removing the site name ''Southern Maryland Wood Treating, Hollywood.''

[FR Doc. 05–2058 Filed 2–3–05; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Chapter 301

[FTR Amendment 2005–01; FTR Case 2005–301]

RIN 3090–AI03

Federal Travel Regulation; Privately Owned Vehicle Mileage Reimbursement

AGENCY: Office Governmentwide Policy, GSA.

ACTION: Final rule.

SUMMARY: This final rule amends the mileage reimbursement rate for use of a privately owned vehicle on official travel to reflect current costs of operation as determined in cost studies conducted by the General Services Administration (GSA). The governing regulation is revised to increase the mileage allowance for advantageous use of a privately owned airplane from $0.995 to $1.07 per mile, the cost of operating a privately owned automobile from $0.375 to $0.405 per mile, and the cost of operating a privately owned motorcycle from $0.285 to $0.305 per mile.

DATES: *Effective Date*: The provisions of this final rule are effective February 4, 2005, and applies to travel performed on or after that date.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat (VIR), Room 4035, GS Building, Washington, DC, 20405, (202) 208–7312, for information pertaining to status or publication schedules. For clarification of content, contact Devoanna R. Reels, Program Analyst, Office of Governmentwide Policy, Travel Management Policy, at (202) 501–3781. Please cite FTR case 2005–301, FTR Amendment 2005–01.

SUPPLEMENTARY INFORMATION:

A. Background

Pursuant to 5 U.S.C. 5707(b), the Administrator of General Services has the responsibility to establish the privately owned vehicle (POV) mileage reimbursement rates. Separate rates are set for airplanes, automobiles (including trucks), and motorcycles. In order to set these rates, GSA is required to conduct periodic investigations, in consultation with the Secretaries of Defense and Transportation, and representatives of Government employee organizations, of the cost of travel and the operation of POVs to employees while engaged on official business. As required, GSA conducted an investigation of the costs of operating a POV and is reporting the cost per mile determination. The results of the investigation have been reported to Congress and a copy of the report appears as an attachment to this document. GSA's cost studies show the Administrator of General Services has determined the per-mile operating costs of a POV to be $1.07 for airplanes, $0.405 for automobiles, and $0.305 for motorcycles. As provided in 5 U.S.C. 5704(a)(1), the automobile reimbursement rate cannot exceed the single standard mileage rate established by the Internal Revenue Service (IRS). The IRS has announced a new single standard mileage rate for automobiles of $0.405 per mile effective January 1, 2005. Additionally, based on updated data for the two-tiered reimbursement rates reflecting costs to an agency of operating a Government-furnished vehicle (GFV), the current reimbursement rate of $0.270 per mile increased to $0.285 per mile (when a GFV is available to an employee). The current reimbursement rate of $0.105 per mile (when a GFV is assigned directly to an employee) will remain the same.

B. Executive Order 12866

This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

C. Regulatory Flexibility Act

This final rule is not required to be published in the **Federal Register** for notice and comment; therefore, the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, does not apply.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FTR do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This final rule is also exempt from congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Part 301–10

Government employees, Travel and transportation expenses.

Dated: January 25, 2005.

Stephen A. Perry,

Administrator of General Services.

■ For the reasons set forth in the preamble, under 5 U.S.C. 5701–5709, GSA amends 41 CFR part 301–10 as set forth below:

PART 301–10—TRANSPORTATION EXPENSES

■ 1. The authority citation for 41 CFR part 301–10 is revised to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); 49 U.S.C. 40118.

■ 2. In section 301–10.303 revise the last three entries in the table to read as follows:

§ 301–10.303 What am I reimbursed when use of a POV is determined by my agency to be advantageous to the Government?

For use of a	Your reimbursement is
* * * * *	* * * * *
Privately owned airplane	[1] $1.07
Privately owned automobile	[1] $0.405
Privately owned motorcycle	[1] $0.305

[1] Per mile.

The following attachment will not appear in the Code of Federal Regulations.

Attachment to Preamble—Report To Congress On The Costs Of Operating Privately Owned Vehicles

5 U.S.C. 5707(b)(1)(A) requires that the Administrator of General Services, in consultation with the Secretary of Defense, the Secretary of Transportation, and representatives of Government employee organizations, conduct periodic investigations of the cost of travel and operation of privately owned vehicles (POVs) (airplanes, automobiles, and motorcycles) to Government employees while on official travel, and report the results to the Congress at least once a year. 5 U.S.C. 5707(b)(2)(B) further requires that the Administrator of General Services determine the average, actual cost per mile for the use of each type of POV based on the results of the cost investigation. Such figures must be reported to the Congress within 5 working days after the cost determination has been made in accordance with 5 U.S.C. 5707(b)(2)(C).

Pursuant to the requirements of 5 U.S.C. 5707(b)(1)(A), the General Services Administration (GSA), in consultation with the Secretary of Defense, the Secretary of Transportation, and representatives of Government employee organizations, conducted an investigation of the cost of operating a privately owned automobile (POA). As provided in 5 U.S.C. 5704(a)(1), the automobile reimbursement rate cannot exceed the single standard mileage rate established by the Internal Revenue Service (IRS). The IRS has announced a new single standard mileage rate for POAs of $0.405 effective January 1, 2005.

As required, GSA is reporting the results of the investigation and the cost per mile determination. Based on cost studies conducted by GSA, I have determined the per-mile operating costs of a POV to be $1.07 for airplanes, $0.405 for POAs, and $0.305 for motorcycles.

I will issue a regulation to increase the current $0.995 to $1.07 for privately owned airplanes, $0.375 to $0.405 for POAs, and $0.285 to $0.305 for privately owned motorcycles. This report to Congress on the cost of operating POVs will be published in the **Federal Register**.

[FR Doc. 05–2124 Filed 2–3–05; 8:45 am]

BILLING CODE 6820–14–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response

Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: Modified Base (1% annual chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect for each listed community prior to this date.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: FEMA makes the final determinations listed below of modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate has resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection.

The modifications are made pursuant to Section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

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

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

The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR Part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for Part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and name of newspaper where notice was published	Chief Executive Officer of community	Effective date of modification	Community No.
Alabama:					
Colbert (FEMA Docket No. D–7557).	City of Muscle Shoals.	Mar. 24, 2004, Mar. 31, 2004, Times Daily.	The Honorable David H. Bradford, Mayor of the City of Muscle Shoals, P.O. Box 2624, Muscle Shoals, Alabama 35662.	Apr. 17, 2004	010047 C
Tuscaloosa (FEMA Docket No. D–7557).	City of Tuscaloosa.	Mar. 24, 2004, Mar. 31, 2004, The Tuscaloosa News.	The Honorable Alvin P. Dupont, Mayor of the City of Tuscaloosa, P.O. Box 2089, Tuscaloosa, Alabama 35403.	June 30, 2004	010203 E
Delaware:					
New Castle (FEMA Docket No. D–7555).	Unincorporated Areas.	Feb. 17, 2004, Feb. 24, 2004, The News Journal.	Mr. Thomas P. Gordon, New Castle County Executive, New Castle County Government Center, 87 Reads Way, New Castle, Delaware 19720.	May 25, 2004	105085 G

State and county	Location	Dates and name of newspaper where notice was published	Chief Executive Officer of community	Effective date of modification	Community No.
New Castle (FEMA Docket No. D–7557).	Unincorporated Areas.	Apr. 2, 2004, Apr. 9, 2004, The News Journal.	Mr. Thomas P. Gordon, New Castle County Executive, New Castle County Government Center, 87 Reads Way, New Castle, Delaware 19720.	July 9, 2004	105085 G
Massachusetts: Barnstable (FEMA Docket No. D–7559).	Town of Falmouth.	Apr. 23, 2004, Apr. 30, 2004, Cape Cod Times.	Mr. Robert L. Whritenour, Jr., Falmouth Town Administrator, 59 Town Hall Square, Falmouth, Massachusetts 02540.	Apr. 16, 2004	255211 G
New Jersey:					
Hudson (FEMA Docket No. D–7555).	Township of North Bergen.	Mar. 31, 2004, Apr. 7, 2004, The Jersey Journal.	The Honorable Nicholas J. Sacco, Mayor of the Township of North Bergen, 4233 Kennedy Boulevard, North Bergen, New Jersey 07047.	Mar. 23, 2004	340225 C
Cape May (FEMA Docket No. D–7555).	Borough of Wildwood Crest.	Feb. 11, 2004, Feb. 18, 2004, The Gazette.	The Honorable John J. Pantalone, Mayor of the Borough of Wildwood Crest, 6101 Pacific Avenue, Wildwood Crest, New Jersey 08260.	Feb. 3, 2004	345330 C
Pennsylvania: Lehigh (FEMA Docket No. D–7553).	Township of South Whitehall.	Feb. 9, 2004, Feb. 16, 2004, The Morning Call.	Mr. Gerald Gasda, Township of South Whitehall Manager, 4444 Walbert Avenue, Allentown, Pennsylvania 18104.	Jan. 28, 2004	420593 D
Puerto Rico: (FEMA Docket No. D–7555).	Commonwealth	Mar. 5, 2004, Mar. 12, 2004, The San Juan Star.	The Honorable Sila M. Calderon, Governor of the Commonwealth of Puerto Rico, Office of the Governor, P.O. Box 9020082, San Juan, Puerto Rico 00902–0082.	June 11, 2004	720000 C
South Carolina:					
York (FEMA Docket No. D–7557).	City of Rock Hill	Mar. 24, 2004, Mar. 31, 2004, The Herald.	The Honorable Doug Echols, Mayor of the City of Rock Hill, P.O. Box 11706, Rock Hill, South Carolina 29731.	June 30, 2004	450196 C
York (FEMA Docket No. D–7557).	Unincorporated Areas.	Mar. 24, 2004, Mar. 31, 2004, The Herald.	Mr. Alfred W. Green, York County Manager, P.O. Box 66, York, South Carolina 29745–0066.	June 30, 2004	450193 C
Vermont: Bennington (FEMA Docket No. D–7555).	Town of Bennington.	Feb. 18, 2004, Feb. 25, 2004, Bennington Banner.	Mr. Stuart Hurd, Bennington Town Manager, P.O. Box 469, 205 South Street, Bennington, Vermont 05201.	Feb. 11, 2004	500013 C
Virginia:					
Culpeper (FEMA Docket No. D–7555).	Town of Culpeper.	Feb. 17, 2004, Feb. 24, 2004, The Culpeper Star.	Mr. J. Brannon Godfrey, Town of Culpeper Manager, 400 South Main Street, Culpeper, Virginia 22701.	May 25, 2004	510042 B
Fairfax (FEMA Docket No. D–7555).	Unincorporated Areas.	Feb. 18, 2004, Feb. 25, 2004, The Washington Times.	Mr. Anthony Griffin, Fairfax County Executive, 12000 Government Center Parkway, Suite 552, Fairfax, Virginia 22035–0066.	May 26, 2004	515525 D
Loudoun (FEMA Docket No. D–7555).	Unincorporated Areas.	Mar. 10, 2004, Mar. 17, 2004, Loudoun Times Mirror.	Mr. Kirby Bowers, Loudoun County Administrator, 1 Harrison Street, S.E., 5th Floor, P.O. Box 7000, Leesburg, Virginia 20177–7000.	June 16, 2004	510090 D
Norfolk (FEMA Docket No. D–7555).	Independent City	Apr. 5, 2004, Apr. 12, 2004, The Virginian-Pilot.	The Honorable Paul D. Fraim, Mayor of the City of Norfolk, 1109 City Hall Building, 810 Union Street, Norfolk, Virginia 23510.	Mar. 29, 2004	510104 E
Prince William (FEMA Docket No. D–7557).	Unincorporated Areas.	Mar. 17, 2004, Mar. 24, 2004, Potomac News.	Mr. Craig Gerhart, Prince William County Executive, 1 County Complex Court, Prince William, Virginia 22192.	June 23, 2004	510119 D
Independent City (FEMA Docket No. D–7557).	City of Winchester.	Mar. 15, 2004, Mar. 22, 2004, Winchester Star.	Mr. Edwin C. Daley, City of Winchester Manager, Rouss City Hall, 15 North Cameron Street, Winchester, Virginia 22601.	Mar. 4, 2004	510173 B

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2120 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket No. FEMA–D–7563]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the Base (1% annual chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

DATES: These modified BFEs are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Director reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

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

The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This interim rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as shown below:

State and county	Location	Dates and name of newspaper where notice was published	Chief Executive Officer of community	Effective date of modification	Community No.
Alabama: Calhoun	Unincorporated Areas.	September 28, 2004; October 5, 2004; *Anniston Star*.	Mr. Ken Joiner, Calhoun County Administrator, 1702 Noble Street, Suite 103, Anniston, Alabama 36201.	September 21, 2004 ..	010013 C
Delaware: New Castle ..	Unincorporated Areas.	August 17, 2004; August 24, 2004; *The News Journal*.	Mr. Thomas P. Gordon, New Castle County Executive, New Castle County Government Center, 87 Reads Way, New Castle, Delaware 19720.	November 23, 2004 ...	105085 G

State and county	Location	Dates and name of newspaper where notice was published	Chief Executive Officer of community	Effective date of modification	Community No.
Florida: Charlotte	Unincorporated Areas.	August 5, 2004; August 12, 2004; *Sun Herald*.	Mr. Bruce Loucks, Charlotte County Administrator, Charlotte County Administration Building, 18500 Murdock Circle, Port Charlotte, Florida 33948.	July 29, 2004	120061 F
Florida: Charlotte	Unincorporated Areas.	September 27, 2004; October 4, 2004; *Sun Herald*.	Mr. Bruce Loucks, Charlotte County Administrator, Charlotte County Administration Building, 18500 Murdock Circle, Port Charlotte, Florida 33948.	September 20, 2004 ..	120061 F
New Jersey: Somerset ..	Township of Warren.	September 9, 2004; *The Echoes Sentinel*.	The Honorable Gary DiNardo, Mayor of the Township of Warren, Warren Township Municipal Building, 46 Mountain Boulevard, Warren, New Jersey 07059.	October 10, 2004	340446 B
North Carolina: Durham	City of Durham ..	August 11, 2004; August 18, 2004; *The Herald Sun*.	The Honorable William V. Bell, Mayor of the City of Durham, Office of the Mayor, 101 City Hall Plaza, Durham, North Carolina 27701.	November 17, 2004 ...	370086 G
South Carolina: Horry ...	Unincorporated Areas.	August 27, 2004; September 3, 2004; *The Sun News*.	Mr. Danny Knight, Horry County Administrator, P.O. Box 1236, Conway, South Carolina 29528.	December 3, 2004	450104 H
South Carolina: Charleston.	City of Isle of Palms.	October 1, 2004; October 8, 2004; *The Post & Courier*.	The Honorable F. Michael Sottile, Mayor of the City of Isle of Palms, P.O. Box 508, Isle of Palms, South Carolina 29451.	September 23, 2004	455416 E
South Carolina: Sumter	Unincorporated Areas.	August 26, 2004; September 2, 2004; *The Item*.	Mr. William T. Noonan, Sumter County Administrator, 13 East Canal Street, Sumter, South Carolina 29150.	December 2, 2004	450182 C

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2119 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: Base (1% annual chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: FEMA makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate, has resolved any appeals resulting from this notification.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

The Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified BFEs are required by the Flood Disaster Protection Act of 1973,

42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)
New Hampshire	
Dover (City), Strafford County (FEMA Docket No. D–7580)	
Boston Harbor:	
At a point immediately downstream of Scammel Bridge	*7
Approximately 100 feet east of northbound lane of Spaulding Turnpike bridge	*7
Maps available for inspection at the Dover City Office, 288 Central Avenue, Dover, New Hampshire.	
WEST VIRGINIA	
McDowell County (Unincorporated Areas) (FEMA Docket No. D–7600)	
Clear Fork:	
Approximately 4,800 feet downstream of County Route 2	*1,409
At the confluence with Wolfpen Branch	*1,479
Wolfpen Branch:	
At the confluence with Clear Fork	*1,479
Approximately 4,440 feet upstream of the confluence with Clear Fork	*1,551
Maps available for inspection at the McDowell County Redevelopment Authority, 90 Wyoming Street, Suite 205, Welch, West Virginia.	

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2123 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: Base (1% annual chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: FEMA makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate, has resolved any appeals resulting from this notification.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

The Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable

standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)
FLORIDA	
Pinellas County (FEMA Docket No. D–7598)	
Stevenson Creek:	
Just upstream of Douglas Avenue	•10
Approximately 350 feet upstream of Southridge Drive	•42
Pinellas County (Unincorporated Areas), City of Clearwater, City of Largo	
Spring Branch:	
Just upstream of Overbrook Road	•10
Approximately 1,500 feet upstream of Highland Avenue	•28
Pinellas County (Unincorporated Areas), City of Clearwater	
Flagler Drive Tributary:	
At the confluence with Stevenson Creek	•14
Approximately 1,250 feet upstream of Keene Road	•62
Pinellas County (Unincorporated Areas), City of Clearwater	
Jeffords Street Tributary:	
At the confluence with Stevenson Creek	•27
Approximately 650 feet upstream of Woodcrest Avenue	•34
Pinellas County (Unincorporated Areas), City of Clearwater	
Ponding Area No. 1:	
Approximately 250 feet northeast of the intersection of Douglas Avenue and Iva Street in the area of Woodlawn Terrace and Idlewood Drive	•21
City of Clearwater	
Crest Lake:	
Approximately 500 feet northeast of the intersection of Gulf-to-Bay Boulevard and Glenwood Avenue	•69
City of Clearwater	
Ponding Area No. 15:	
Approximately 350 feet southwest of the intersection of South Missouri Avenue and Beleair Road and 350 feet northeast of the intersection of Ponce De Leon Boulevard and Greenwood Avenue	•62
Pinellas County (Unincorporated Areas), City of Clearwater	
Ponding Area No. 2:	
At the intersection of Druid Road and Duncan Avenue	•61
City of Clearwater	
Hammond Creek:	
At the confluence with Stevenson Creek	•10
Approximately 325 feet upstream of Highland Avenue	•28
Pinellas County (Unincorporated Areas), City of Clearwater	
Ponding Area No. 3:	
Approximately 150 feet northeast of the intersection of Keene Road and Magnolia Drive	•46
Pinellas County (Unincorporated Areas), City of Clearwater	
Ponding Area No. 4:	
Approximately 150 feet southwest of the intersection of Keene Road and Magnolia Drive	•43
Pinellas County (Unincorporated Areas)	
Ponding Area No. 5:	
Approximately 50 feet southeast of the intersection of Keene Road and Magnolia Drive	•42
Pinellas County (Unincorporated Areas)	
Lake Rhonda:	
Approximately 100 feet southeast of the intersection of Magnolia Drive and Keene Road	•35
Pinellas County (Unincorporated Areas)	
Ponding Area No. 6:	
Approximately 100 feet southwest of the intersection of Highland Avenue and Belleair Road	•47
Pinellas County (Unincorporated Areas), City of Clearwater	
Ponding Area No. 7:	
Approximately 500 feet northeast of the intersection of Missouri Avenue and Bellevue Boulevard	•61
City of Clearwater	
Ponding Area No. 8:	
Approximately 1,000 feet southeast of the intersection of Lakeview Road and Evergreen Drive in the vicinity of Byron Court	•36
City of Clearwater	
Clear View Lake:	
Approximately 1,000 feet northwest of Sunset Point Road and Keene Road	•57
City of Clearwater	
Ponding Area No. 9:	
At the intersection of North Greenwood Avenue and Palmetto Street	•20
City of Clearwater	
Lake Bellevue Area No. 1:	
Approximately 1,000 feet northeast of the intersection of Lakeview Road and Greenwood Avenue	•39
City of Clearwater	
Lake Bellevue Area No. 2:	
Approximately 500 feet north of the intersection of Lakeview Road and Greenwood Avenue	•40
City of Clearwater	
Lake Bellevue Area No. 3:	
Approximately 250 feet northwest of the intersection of Lakeview Road and Greenwood Avenue	•41
City of Clearwater	
Lake Bellevue Area No. 4:	
Approximately 250 feet southwest of the intersection of Lakeview Road and Greenwood Avenue	•42
City of Clearwater	
Lake Bellevue Area No. 5:	
Approximately 1,500 feet southwest of the intersection of Lakeview Road and Greenwood Avenue	•43
City of Clearwater	
Lake Bellevue Area No. 6:	
Approximately 600 feet north of the intersection of Woodlawn Avenue and South Myrtle Avenue	•44
City of Clearwater	
Lake Bellevue Area No. 7:	
Approximately 400 feet north of the intersection of Woodlawn Avenue and South Myrtle Avenue	•45
City of Clearwater	
Lake Bellevue Area No. 8:	
Approximately 250 feet north of the intersection of Woodlawn Avenue and South Myrtle Avenue	•46
City of Clearwater	
Lake Bellevue Area No. 9:	
Approximately 100 feet north of the intersection of Woodlawn Avenue and South Myrtle Avenue	•47
City of Clearwater	
Lake Bellevue Area No. 10:	

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)
Approximately 100 feet south of the intersection of Woodlawn Avenue and South Myrtle Avenue 2	•50
City of Clearwater	
Lake Bellevue Area No. 11:	
Approximately 500 feet south of the intersection of Woodlawn Avenue and South Myrtle Avenue 2	•51
City of Clearwater	
Lake Bellevue Area No. 12:	
Approximately 100 feet south of the intersection of Howard Street and South Myrtle Avenue 2	•53
City of Clearwater	
Lake Bellevue Area No. 13:	
Approximately 250 feet south of the intersection of Howard Street and South Myrtle Avenue 2	•54
City of Clearwater	
Lake Bellevue Area No. 14:	
Approximately 350 feet south of the intersection of Howard Street and South Myrtle Avenue 2	•55
City of Clearwater	
Lake Bellevue Area No. 15:	
Approximately 250 feet northeast of the intersection of Belleair Road and South Myrtle Avenue 2	•56
City of Clearwater	
Lake Bellevue Area No. 16:	
Approximately 500 feet southeast of the intersection of Belleair Road and South Myrtle Avenue 2	•57
Pinellas County (Unincorporated Areas), City of Clearwater	
Hobart Lake:	
Approximately 200 feet southwest of the intersection of Casler Avenue and Palmetto Street	•67
City of Clearwater	
Ponding Area No. 10:	
Approximately 1,000 feet west of Keene Road and 150 feet north of Hobart Lake	•66
City of Clearwater	
Lake Lucille:	
Approximately 100 feet southeast of the intersection of Sherwood Street and Nelson Avenue	•60
City of Clearwater	
Ponding Area No. 11:	
Approximately 700 feet west of the intersection of Sherwood Street and Keene Road	•64
City of Clearwater	
St. Andrews Lake:	
Approximately 1,000 feet northeast of the intersection of Airport Drive and Keene Road	•68
City of Clearwater	
Ponding Area No. 13:	
At the intersection of North Madison Avenue and Carlton Street	•16
City of Clearwater	
Ponding Area No. 14:	
Generally following the southern side of CSX Transportation tracks in the area where North Greenwood Avenue intersects with Plaza Street	•24
City of Clearwater	
Highland Lake:	
Approximately 200 feet southwest of the intersection of Valencia Street and Lake Avenue	•47
Pinellas County (Unincorporated Areas)	
Ponding Area No. 16:	
Approximately 3,000 feet northwest of intersection of Marilyn Street and Hercules Avenue	•68
City of Clearwater	
Ponding Area No. 17:	
Approximately 1,500 feet northwest of the intersection of Marilyn Street and Hercules Avenue	•69
City of Clearwater	
Ponding Area No. 12:	
At the intersection of Palmetto Street and Pennsylvania Avenue	•21
City of Clearwater	
City of Clearwater	
Maps available for inspection at the City of Clearwater Engineering Department, 100 South Myrtle Avenue, Suite 220, Clearwater, Florida.	
City of Largo	
Maps available for inspection at the Largo City Hall, 201 Highland Avenue, Largo, Florida.	
Pinellas County (Unincorporated Areas)	
Maps available for inspection at the Pinellas County Building, 315 Court Street, Clearwater, Florida.	
ILLINOIS	
Cook County (FEMA Docket No. D–7526)	
Addison Creek:	
Approximately 360 feet upstream of 21st Street	*621
Approximately 180 feet upstream of Tri-State Tollway	*656
Village of Bellwood, Village of Broadview, Cook County (Unincorporated Areas), Village of Hillside, Village of Maywood, Village of Melrose Park, City of Northlake, Village of Stone Park, Village of Westchester	
Village of Bellwood	
Maps available for inspection at the Bellwood Village Hall, Building Department, 3200 Washington Boulevard, Bellwood, Illinois.	
Village of Broadview	
Maps available for inspection at the Broadview Village Hall, 2350 South 25th Avenue, Broadview, Illinois.	
Cook County (Unincorporated Areas)	
Maps available for inspection at the Cook County Department of Building and Zoning, 69 West Washington Street, Chicago, Illinois.	
Village of Hillside	
Maps available for inspection at the Hillside Village Hall, 425 Hillside Avenue, Hillside, Illinois.	
Village of Maywood	
Maps available for inspection at the Maywood Village Hall, Building and Zoning Department, 40 Madison Street, Maywood, Illinois.	
Village of Melrose Park	
Maps available for inspection at the Melrose Park Village Hall, Building Department, 1000 North 25th Avenue, Melrose Park, Illinois.	
City of Northlake	
Maps available for inspection at the Northlake City Hall, Building Department, 55 East North Avenue, Northlake, Illinois.	
Village of Stone Park	
Maps available for inspection at the Stone Park Village Hall, Office of Building Inspections, 1629 North Mannheim Road, Stone Park, Illinois.	
Village of Westchester	
Maps available for inspection at the Westchester Village Hall, Building Department, 10300 Roosevelt Road, Westchester, Illinois.	
NEW HAMPSHIRE	
Rockingham County (FEMA Docket No. D–7578)	
Exeter River:	
Approximately 850 feet northeast of the intersection of Great Oak and Pheasant Run Drive at the corporate limits of the Town of Chester and the Town of Raymond	*165
Town of Chester	
Powwow Pond:	
North of Boston and Maine Railroad	*119
South of Boston and Maine Railroad	*118

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)
Town of East Kingston	
Lamprey River:	
Approximately 950 feet downstream of Prescott Road	*164
Approximately 300 feet upstream of Prescott Road	*167
Town of Epping	
Piscassic River:	
Approximately 0.57 mile downstream of upstream corporate limits	*105
At upstream corporate limits	*108
Town of Exeter	
Piscataqua River:	
North of State Route 18 (East of Pierce Island)	*9
Town of New Castle	
Country Pond:	
Entire shoreline within community	*121
Town of Newton	
Little River No. 3:	
At upstream corporate limits	*103
At downstream corporate limits	*103
Town of Newton	
Flatrock Branch:	
At confluence with Shadow Lake	*162
Approximately 150 feet downstream of Doiron Road	*163
Town of Salem	
Squamscott River:	
At downstream side of Boston and Maine Railroad bridge	*7
At downstream corporate limits	*7
Town of Stratham	
Lamprey River:	
Approximately 1.3 miles upstream of Alternate Route 101	*217
Approximately 1.77 miles upstream of Alternate Route 101	*217
Town of Candia	
Great Bay/Little Bay:	
Entire shoreline within the community	*7
Town of Newington	
Piscataqua River:	
From the Spaulding Turnpike bridge to the Greenland/Portsmouth corporate limits	*9
Town of Newington	
Pickering Brook:	
At the Greenland/Portsmouth corporate limits	*27
Approximately 2,300 feet upstream of Greenland/Portsmouth corporate limits	*27
City of Portsmouth	
Town of Candia:	
Maps available for inspection at the Candia Town Office, 74 High Street, Candia, New Hampshire.	
Town of Chester:	
Maps available for inspection at the Town of Chester Municipal Office Building, 84 Chester Street, Chester, New Hampshire.	
Town of East Kingston:	
Maps available for inspection at the East Kingston Town Office, 24 Depot Road, East Kingston, New Hampshire.	
Town of Epping:	
Maps available for inspection at the Epping Town Hall, 157 Main Street, Epping, New Hampshire.	
Town of Exeter:	
Maps available for inspection at the Exeter Town Office, 10 Front Street, Exeter, New Hampshire.	
Town of Newington:	
Maps available for inspection at the Newington Town Office, 205 Nimble Hill Road, Newington, New Hampshire.	
Town of Newton:	
Maps available for inspection at the Newton Town Hall, Town Hall Road, Newton, New Hampshire.	
City of Portsmouth:	
Maps available for inspection at the City of Portsmouth Municipal Complex, Planning Department, 3rd Floor, 1 Junkins Avenue, Portsmouth, New Hampshire.	
Town of New Castle:	
Maps available for inspection at the New Castle Town Office, 49 Main Street, New Castle, New Hampshire.	
Town of Salem:	
Maps available for inspection at the Salem Town Office, 33 Geremonty Drive, Salem, New Hampshire.	
Town of Stratham:	
Maps available for inspection at the Stratham Town Office, 10 Bunker Hill Avenue, Stratham, New Hampshire.	
WEST VIRGINIA	
Cabell County and City of Huntington (FEMA Docket No. D–7598)	
Ohio River:	
At the downstream county boundary	•550
Approximately 8 miles upstream of confluence of Goose Run	•561
Cabell County (Unincorporated Areas), City of Huntington	
Fourpole Creek:	
Approximately 200 feet upstream of the Ohio River	•538
Approximately 2,400 feet upstream of Prices Creek Road	•703
Cabell County (Unincorporated Areas), City of Huntington	
Indian Fork:	
Approximately 1,160 feet upstream of confluence with Mud Creek	•587
Approximately 250 feet upstream of Ridge Run Road	•640
Cabell County (Unincorporated Areas)	
Kilgore Creek:	
At the confluence with Indian Fork	•587
Approximately 500 feet upstream of the confluence of Little Creek	•611
Cabell County (Unincorporated Areas)	
Lee Creek:	
At the confluence with Kilgore Creek	•590
Approximately 6,500 feet upstream of Interstate Route 64	•660
Cabell County (Unincorporated Areas)	
Charley Creek:	
Approximately 1,820 feet upstream of confluence with Mud Creek	•602
Approximately 2,250 feet downstream of Wolfpen Hollow Road	•615
Cabell County (Unincorporated Areas)	
Little Creek:	
At the confluence with Kilgore Creek	•610
Approximately 750 feet upstream of the confluence with Kilgore Creek	•611
Cabell County (Unincorporated Areas)	
Arlington Boulevard Tributary:	
Backwater area along Norwood Road	•613
At the confluence with Guyandotte River	•554
Approximately 150 feet downstream of Arlington Boulevard	•554
Cabell County (Unincorporated Areas)	
Grapevine Branch:	
At the confluence with Fourpole Creek	•590
Approximately 1,050 feet upstream of the confluence with Fourpole Creek	•590
Cabell County (Unincorporated Areas), City of Huntington	
Cabell County (Unincorporated Areas)	

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)
Maps available for inspection at the Cabell County Office of Grants, Planning and Permits, Cabell County Courthouse, Room 314, Huntington, West Virginia.	
City of Huntington	
Maps available for inspection at the City of Huntington Department of Development and Planning, 800 Fifth Street, Room 14, Huntington, West Virginia.	

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2122 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: Base (1% annual chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: FEMA makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate, has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

The Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)
ALABAMA	
Cullman County (FEMA Docket No. D–7594)	
Mud Creek:	
At Interstate 31	*533
Approximately 800 feet upstream of State Route 91	*537
Cullman County (Unincorporated Areas), City of Hanceville	
Bavar Creek:	
Approximately 2,400 feet downstream of County Route 37	*567
At Section Line Road	*692
Town of Good Hope	
Ryan Creek:	
Approximately 1,000 feet downstream of County Road 38	*643
Approximately 0.4 mile upstream of 16th Street Southeast	*713
Cullman County (Unincorporated Areas), City of Cullman	
Wolf Creek:	
At the confluence with Ryan Creek	*676
Approximately 0.3 mile upstream of Briarwood Drive Southeast	*691
City of Cullman	
Cullman County (Unincorporated Areas)	
Maps available for inspection at the Cullman County Commission, 500 Second Avenue SW., Room 202, Cullman, Alabama.	
City of Cullman	
Maps available for inspection at the City of Cullman Building Department, 201 2nd Avenue, Cullman, Alabama.	

Source of flooding and location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)
City of Good Hope	
Maps available for inspection at the Good Hope City Hall, 134 Town Hall Drive, Cullman, Alabama.	
City of Hanceville	
Maps available for inspection at the Hanceville City Hall, 112 Main Street SE., Hanceville, Alabama.	
City of Roanoke, Randolph County (FEMA Docket No. D–7596)	
Graves Creek:	
Approximately 1,000 feet upstream of the confluence with High Pine Creek	*733
Approximately 1.2 miles upstream of U.S. Highway 431	*770
City of Roanoke	
City of Roanoke	
Maps available for inspection at the Roanoke City Hall, 809 East Main Street, Roanoke, Alabama.	

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2121 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

Proposed Rules

Federal Register
Vol. 70, No. 23
Friday, February 4, 2005

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

Agricultural Marketing Service

7 CFR Part 993

[Docket No. FV05–993–1 PR]

Dried Prunes Produced in California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule would increase the assessment rate established for the Prune Marketing Committee (committee) under Marketing Order No. 993 for the 2004–05 and subsequent crop years from $4.00 to $6.00 per ton of salable dried prunes. The committee locally administers the marketing order which regulates the handling of dried prunes grown in California. Authorization to assess dried prune handlers enables the committee to incur expenses that are reasonable and necessary to administer the program. The committee recommended a higher assessment rate because the 2004–05 crop is very small, and the higher assessment rate is needed to generate funds to meet program expenses and provide an adequate financial reserve. The crop year begins August 1 and ends July 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by March 7, 2005.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or e-mail: *moab.docketclerk@usda.gov*, or Internet: *http://www.regulations.gov*. Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.ams.usda.gov/fv/moab.html*.

FOR FURTHER INFORMATION CONTACT: Toni Sasselli, Program Analyst, or Terry Vawter, Marketing Specialist, California Marketing Field Office, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, suite 102B, Fresno, California 93721; telephone: (559) 487–5901; Fax (559) 487–5906; or George Kelhart, Technical Advisor, 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.

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 rule is issued under Marketing Agreement No. 110 and Marketing Order No. 993, both as amended (7 CFR part 993), regulating the handling of dried prunes grown in California, hereinafter referred to as the ''order.'' The marketing agreement and order are 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 rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, California dried prune handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as proposed herein would be applicable to all assessable dried prunes beginning August 1, 2004, and continue until amended, suspended, or terminated. This rule 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. Such 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 rule would increase the assessment rate established for the committee for the 2004–05 and subsequent crop years from $4.00 to $6.00 per ton of salable dried prunes.

The California dried prune marketing order provides authority for the committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the committee are producers and handlers of California dried prunes. They are familiar with the committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

The committee recommended an assessment rate of $4.00 per salable ton of prunes for the 2004–05 and subsequent crop years on June 23, 2004. USDA approved that assessment rate and it was published in the **Federal Register** on September 28, 2004 (69 FR 55733). That assessment rate was to continue in effect from crop year to crop year unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the committee or other information available to USDA. At the time of the June 23, 2004, meeting, the

prune crop was expected to be 68,950 salable tons.

The committee met again on December 8, 2004, and unanimously recommended an increased assessment rate of $6.00 per ton of salable dried prunes and an increase in 2004–05 expenditures to $283,218. At its June 23, 2004, meeting, the committee recommended expenditures totaling $275,800. The proposed assessment rate of $6.00 per ton is $2.00 higher than the rate currently in effect, and $4.00 per ton more than the assessment rate in effect during the 2003–2004 crop year.

The committee recommended a higher assessment rate because a very small crop was received by handlers during the crop year. The salable prune production this crop year is expected to be only 47,203 tons, the smallest crop since 1918. The assessment rate of $6.00 per ton is expected to provide sufficient funds for committee operations this year and provide an adequate financial reserve.

In comparison, the budgeted expenditures for the 2003–2004 crop year were $322,022 and the assessment rate was $2.00 per salable ton of prunes, based upon an estimated crop of 170,500 salable tons.

The following table compares the proposed major budget expenditures recommended by the committee on December 8, 2004, and major budget expenditures in the previously-approved 2004–05 budget.

Budget expense categories	Approved budget 2004–05	Proposed budget 2004–05
Total Personnel Salaries	$181,335	$178,335
Total Operating Expenses	84,931	75,431
Reserve for Contingencies	9,534	29,452

The assessment rate recommended by the committee was derived by dividing anticipated expenses by the estimated salable tons of California dried prunes. Production of dried prunes for the year is estimated to be 47,203 salable tons, which should provide $283,218 in assessment income. Income derived from handler assessments is expected to be adequate to cover budgeted expenses.

The committee is authorized to use excess assessment funds from the 2003–04 crop year (currently estimated at $96,702) for up to 5 months beyond the end of the crop year to meet 2004–05 crop year expenses. At the end of the 5-month period, the committee must refund or credit excess funds to handlers, as prescribed by § 993.81(c).

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the committee would continue to meet prior to or during each crop year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of committee meetings are available from the committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The committee's 2004–05 budget and those for subsequent crop years would be reviewed and, as appropriate, approved by USDA.

Initial 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 rule on small entities. Accordingly, AMS has prepared this initial 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 the 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 1,100 producers of dried prunes in the production area and approximately 22 handlers subject to regulation under the marketing order. The Small Business Administration (13 CFR 121.201) defines small agricultural producers as those whose annual receipts are less than $750,000, and small agricultural service firms as those whose annual receipts are less than $5,000,000.

Eight of the 22 handlers (36.4 percent) shipped over $5,000,000 of dried prunes and could be considered large handlers by the Small Business Administration. Fourteen of the 22 handlers (63.6 percent) shipped under $5,000,000 of dried prunes and could be considered small handlers. An estimated 32 producers, or less than 3 percent of the 1,100 total producers, would be considered large growers with annual incomes over $750,000. The majority of handlers and producers of California dried prunes may be classified as small entities.

This rule would increase the assessment rate established for the committee and collected from handlers for the 2004–05 and subsequent crop years from $4.00 to $6.00 per ton of salable dried prunes. The committee unanimously recommended revised 2004–05 expenditures of $283,218 and an increased assessment rate of $6.00 per ton of salable dried prunes at the meeting on December 8, 2004. The recommended expenditures are slightly higher than the Committee's initial estimate of $275,800 for 2004–05. The proposed assessment rate of $6.00 per ton is $2.00 higher than the current rate. The quantity of salable dried prunes for the 2004–05 crop year is now estimated at 47,203 salable tons. The Committee's earlier estimate was 68,950 salable tons. The $6.00 rate should provide $283,218 in assessment income ($6 \times 47{,}203$) and be adequate to meet this year's expenses.

The following table compares the proposed major budget expenditures recommended by the committee on December 8, 2004 and major budget expenditures in the previously-approved 2004–05 budget.

Budget expense categories	Approved budget 2004–05	Proposed budget 2004–05
Total Salaries	$181,335	$178,331
Operating Expenses	84,931	75,431
Reserve for Contingencies	9,534	29,452

Prior to arriving at its budget of $283,218, the committee considered information from various sources, such as the committee's Executive Subcommittee. An alternative to this action would be to continue with the $4.00 per ton assessment rate. However, an assessment rate of $4.00 per ton in combination with the estimated crop of 47,203 salable tons would not generate sufficient monies to fund all the budget items for 2004–05 and provide an adequate financial reserve. The assessment rate of $6.00 per ton of salable dried prunes was determined by dividing the total recommended budget by the estimated salable dried prunes.

The committee is authorized to use excess assessment funds from the 2003–04 crop year (currently estimated at $96,702) for up to 5 months beyond the end of the crop year to fund 2004–05 crop year expenses. At the end of the 5-month period, the committee must

refund or credit excess funds to handlers, as prescribed by § 993.81(c). Anticipated assessment income collected during 2004–05 would be adequate to cover authorized expenses.

The grower price for the 2004–05 crop year is expected to average about $750 per salable ton of dried prunes. Based on an estimated 47,203 salable tons of dried prunes, assessment revenue during the 2004–05 crop year is expected to be less than 1 percent of the total expected grower revenue.

This action would increase the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be offset by the benefits derived by the operation of the marketing order. In addition, the committee's meeting was widely publicized throughout the California dried prune industry and all interested persons were invited to attend the meeting and participate in committee deliberations on all issues. Like all committee meetings, the December 8, 2004, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large California dried prune handlers. 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.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

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.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. Thirty days is deemed appropriate because: (1) The 2004–05 crop year began on August 1, 2004, and the marketing order requires that the rate of assessment for each crop year apply to all assessable prunes handled during such crop year; (2) the committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis; and (3) handlers are aware of this action which was unanimously recommended by the committee at a public meeting and is similar to other assessment rate actions issued in past years.

List of Subjects in 7 CFR Part 993

Marketing agreements, Plums, Prunes, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 993 is proposed to be amended as follows:

PART 993—DRIED PRUNES PRODUCED IN CALIFORNIA

1. The authority citation for 7 CFR part 993 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 993.347 is revised to read as follows:

§ 993.347 Assessment rate.

On and after August 1, 2004, an assessment rate of $6.00 per ton is established for California dried prunes.

Dated: January 31, 2005.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 05–2153 Filed 2–3–05; 8:45 am]

BILLING CODE 3410–02–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Chap. VII

Request for Burden Reduction Recommendation; Safety and Soundness and Anti-Money Laundering Regulations; Economic Growth and Regulatory Paperwork Reduction Act of 1996 Review

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice of regulatory review; request for comments.

SUMMARY: The NCUA Board is continuing its review of its regulations to identify outdated, unnecessary, or unduly burdensome regulatory requirements imposed on federally-insured credit unions pursuant to the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (EGRPRA). Today, NCUA requests comments and suggestions on ways to reduce burden in rules that govern safety and soundness and anti-money laundering, consistent with our statutory obligations. All comments are welcome.

We will analyze the comments received and propose burden reducing changes to our regulations where appropriate. Some suggestions for burden reduction might require legislative changes. Where legislative changes would be required, we will consider the suggestions in recommending appropriate changes to Congress.

DATES: Comment must be received on or before May 5, 2005.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- NCUA Web Site: *http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html.* Follow the instructions for submitting comments.
- E-mail: Address to *regcomments@ncua.gov.* Include ''[Your name] Comments on Fourth EGRPRA Notice'' in the e-mail subject line.
- Fax: (703) 518–6319. Use the subject line described above for e-mail.
- Mail: Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- Hand Delivery/Courier: Same as mail address.

Public inspection: All public comments are available on the agency's Web site at *http://www.ncua.gov/RegulationsOpinionsLaws/comments* as submitted, except as may not be possible for technical reasons. Public comments will not be edited to remove any identifying or contact information. Paper copies of comments may be inspected in NCUA's law library, at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6546 or send an e-mail to *OGC_Mail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Ross P. Kendall, Staff Attorney, Office of General Counsel, at the above address or telephone (703) 518–6562.

SUPPLEMENTARY INFORMATION:

I. Introduction

NCUA seeks public comment and suggestions on ways it can reduce regulatory burdens consistent with our statutory obligations. Today, we request input to help identify which requirements in two regulatory categories—Safety and Soundness and Anti-Money Laundering—are outdated, unnecessary, or unduly burdensome.

The rules in these categories are listed in a chart at the end of this notice. The EGRPRA review supplements and complements the reviews of regulations that NCUA conducts under other laws and its internal policies.

We specifically invite comment on the following issues: Whether statutory changes are needed; whether the regulations contain requirements that are not needed to serve the purposes of the statutes they implement; the extent to which the regulations may adversely affect competition; the cost of compliance associated with reporting, recordkeeping, and disclosure requirements, particularly on small credit unions; whether any regulatory requirements are inconsistent or redundant; and whether any regulations are unclear.

In drafting this notice, the NCUA participated as part of the EGRPRA planning process with the Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and Office of Thrift Supervision (Agencies). Because of the unique circumstances of federally-insured credit unions and their members, NCUA is issuing a separate notice from the four bank regulatory agencies, which are issuing a joint notice. NCUA's notice is consistent and comparable with the joint notice, except on issues that are unique to credit unions. For example, unlike the bank regulators, NCUA does not have a regulatory category governing securities activities, and so its notice makes no reference to that subject.

II.

A. The EGRPRA Review Requirements and NCUA's Proposed Plan

This notice is part of the regulatory review required by section 2222 of EGRPRA.[1] The NCUA described the review requirements in our initial **Federal Register** notice, published on July 3, 2003 (68 FR 39863). As we noted at that time, we anticipate that the EGRPRA review's overall focus on the ''forest'' of regulations will offer a new perspective in identifying opportunities to reduce regulatory burden. We must, of course, assure that the effort to reduce regulatory burden is consistent with applicable statutory mandates and provides for the continued safety and soundness of federally-insured credit unions and appropriate consumer protections.

The EGRPRA review required that NCUA categorize our regulations by type. Our July 3, 2003, **Federal Register** publication identified ten broad categories for our regulations.

The categories are:

1. Applications and Reporting
2. Powers and Activities
3. Agency Programs
4. Capital
5. Consumer Protection
6. Corporate Credit Unions
7. Directors, Officers and Employees
8. Money Laundering
9. Rules of Procedure
10. Safety and Soundness

To spread the work of commenting on and reviewing the categories of rules over a reasonable period of time, we proposed to publish one or more categories of rules approximately every six months between 2003 and 2006 and provide a 90-day comment period for each publication. We asked for comment on all aspects of our plan, including: The categories, the rules in each category, and the order in which we should review the categories. Because the NCUA was eager to begin reducing unnecessary burden where appropriate, our initial notice also published the first two categories of rules for comment (Applications and Reporting and Powers and Activities). NCUA published its second notice, soliciting comment on consumer protection rules in the lending area, on February 4, 2004 (69 FR 5300), and its third notice, relating to other consumer protection rules, on July 8, 2004 (69 FR 41202). All our covered categories of rules must be published for comment and reviewed by the end of September 2006.

The EGRPRA review then requires the Agencies to: (1) Publish a summary of the comments we received, identifying and discussing the significant issues raised in them; and (2) eliminate unnecessary regulatory requirements. Within 30 days after the Agencies publish the comment summary and discussion, the Federal Financial Institutions Examination Council (FFIEC), which is an interagency body to which all of the Agencies belong, must submit a report to Congress. This report will summarize significant issues raised by the public comments and the relative merits of those issues. It will also analyze whether the appropriate federal financial institution regulatory agency can address the burdens by regulation, or whether the burdens must be addressed by legislation.

B. Public Response and NCUA's Current Plan

NCUA received eight comments in response to its first notice, four comments in response to its second notice, and six in response to the third notice. The comments have been posted on the interagency EGRPRA Web site, *http://www.EGRPRA.gov,* and can be viewed by clicking on ''Comments.'' We are actively reviewing the feedback received about specific ways to reduce regulatory burden, as well as conducting our own analyses. Because the main purpose of this notice is to request comment on the next category of regulations, we will not discuss specific recommendations that we have received in response to our earlier notices here. However, as we develop initiatives to reduce burden on specific subjects in the future—whether through regulatory, legislative, or other channels—we will discuss the public's recommendations that relate to our proposed actions.

On June 22, 2004, NCUA Chairman JoAnn Johnson testified about regulatory reform before the Senate Committee on Banking, Housing and Urban Affairs. Representatives from the federal banking agencies also testified, as did key private sector representatives from the financial institution industry. On August 27, Senator Mike Crapo, who is leading a financial services regulatory reform effort for the Senate Banking Committee, released a matrix detailing more than 130 burden reduction proposals that were made at the June 2004 hearing.

III. Request for Comment on Safety and Soundness and Anti-Money Laundering Rules Category

NCUA is asking the public to identify the ways in which the rules in the category of safety and soundness and anti-money laundering may be outdated, unnecessary, or unduly burdensome. If the implementation of a comment would require modifying a statute that underlies the regulation, the comment should, if possible, identify the needed statutory change. The rules in this category are listed in the chart below. We note that the U.S. Treasury Department also administers rules under the Bank Secrecy Act that apply to Federal credit unions. These rules are beyond the jurisdiction of the NCUA. To the extent, however, that we receive comment raising significant issues about these rules, we will assure that the issues are identified in the FFIEC report to Congress and will notify the Treasury Department of the substance of the comments.

We encourage comments that not only deal with individual rules or requirements but also pertain to certain product lines. A product line approach is consistent with EGRPRA's focus on how rules interact, and may be

[1] Pub. Law 104–208, div. A, title II, section 2222, 110 Stat. 3009–414; codified at 12 U.S.C. 3311.

especially helpful in exposing redundant or potentially inconsistent regulatory requirements. We recognize that commenters using a product line approach may want to make recommendations about rules that are not in our current request for comment. They should do so since the EGRPRA categories are designed to stimulate creative approaches rather than limiting them. We note, in this respect, that NCUA included both its lending and investment rules in its first EGRPRA notice (68 FR 39863, July 3, 2003), and that the same rules are included with this notice as well. The first notice solicited comment on the category of Powers and Activities, while in this notice we are focused on Safety and Soundness issues. Because aspects of both rules fall into each category, we are including them for this second time. There are several other rules, which we have placed in other categories, that also involve safety and soundness. Finally, we note that, as related to state chartered, federally insured credit unions, the inclusion of subpart B of 12 CFR part 748 in this category is a shorthand reference to a number of rules codified elsewhere in our regulations that have a significant safety and soundness impact. Comment is invited on all of these rules.

Specific issues to consider. While all comments are welcome, NCUA specifically invites comment on the following issues:

- *Need for statutory change.* Do any of the statutory requirements underlying these regulations impose redundant, conflicting or otherwise unduly burdensome requirements? Are there less burdensome alternatives?
- *Need and purpose of the regulations.* Are the regulations consistent with the purposes of the statutes that they implement? Have circumstances changed so that the regulation is no longer necessary? Do changes in the financial products and services offered to consumers suggest a need to revise certain regulations or statutes? Do any of the regulations impose compliance burdens not required by the statutes they implement?
- *General approach/flexibility.* Generally, is there a different approach to regulating that NCUA could use that would achieve statutory goals while imposing less burden? Do any of the regulations in this category or the statutes underlying them impose unnecessarily inflexible requirements?
- *Effect of the regulations on competition.* Do any of the regulations in this category or the statutes underlying them create competitive disadvantages for credit unions compared to another part of the financial services industry?
- *Reporting, recordkeeping and disclosure requirements.* Do any of the regulations in this category or the statutes underlying them impose particularly burdensome reporting, recordkeeping or disclosure requirements? Are any of these requirements similar enough in purpose and use so that they could be consolidated? What, if any, of these requirements could be fulfilled electronically to reduce their burden? Are any of the reporting or recordkeeping requirements unnecessary to demonstrate compliance with the law?
- *Consistency and redundancy.* Do any of the regulations in this category impose inconsistent or redundant regulatory requirements that are not warranted by the purposes of the regulation?
- *Clarity.* Are the regulations in this category drafted in clear and easily understood language?
- *Burden on small insured institutions.* NCUA has a particular interest in minimizing burden on small insured credit unions (those with less than $10 million in assets). More than half of federally-insured credit unions are small—having $10 million in assets or less—as defined by NCUA in Interpretative Ruling and Policy Statement 03–2, Developing and Reviewing Government Regulations. NCUA solicits comment on how any regulations in this category could be changed to minimize any significant economic impact on a substantial number of small credit unions.

NCUA appreciates the efforts of all interested parties to help us eliminate outdated, unnecessary or unduly burdensome regulatory requirements.

IV. Regulations About Which Burden Reduction Recommendations Are Requested Currently

SAFETY AND SOUNDNESS AND ANTI-MONEY LAUNDERING RULES

Subject	Code of Federal Regulations (CFR) Citation
Lending	12 CFR 701.21.
Investments	12 CFR part 703.
Supervisory Committee Audits and Verifications.	12 CFR part 715.
Security Programs	12 CFR 748.0.
Guidelines for Safeguarding Member Information.	12 CFR 748, appendix A.
Records Preservation Program and Record Retention Index.	12 CFR part 749.

SAFETY AND SOUNDNESS AND ANTI-MONEY LAUNDERING RULES—Continued

Subject	Code of Federal Regulations (CFR) Citation
Appraisals	12 CFR part 722.
Examination	12 CFR 741.1.
Rules that Apply to Federally insured state-chartered credit unions.	12 CFR part 741, subpart B.
Report of Crimes or Suspected Crimes.	12 CFR 748.1(c).
Bank Secrecy Act	12 CFR 748.2.

By the National Credit Union Administration Board on January 25, 2005.

Mary Rupp,

Secretary of the Board.

[FR Doc. 05–2205 Filed 2–3–05; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–129709–03]

RIN 1545–BC34

Prohibited Allocations of Securities in an S Corporation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing.

SUMMARY: This document contains corrections to a notice of proposed rulemaking that was published in the **Federal Register** on December 17, 2004 (69 FR 75492), relating to prohibited allocations of securities in an S Corporation.

FOR FURTHER INFORMATION CONTACT: John Ricotta at (202) 622–6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking (REG–129709–03) that is the subject of this correction is under section 409 of the Internal Revenue Code.

Need for Correction

As published the notice of proposed rulemaking (REG–129709–03), contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing (REG–129709–03), which was the subject of FR Doc. 04–27295, is corrected as follows:

1. On page 75492, column 2, in the preamble under the caption **DATES,** the second sentence from the bottom of the paragraph, the language ''10 a.m. must be received by March 14,'' is corrected to read ''10 a.m. must be received by March 30,''.

2. On page 75492, column 2, in the preamble under the caption **ADDRESSES**, the last sentence, the language ''REG–129703–03).'' is corrected to read ''REG–129709–03).''.

3. On page 75492, column 3, in the preamble under the caption Comments and Requests for a Public Hearing, paragraph 3, line 8, the language ''March 14, 2005. A period of 10 minutes'' is corrected to read ''March 30, 2005. A period of 10 minutes''.

PART 1—[AMENDED]

§ 1.409(p)–1 [Corrected]

4. On page 75493, column 1, the section title for § 1.409(p)-1, the language ''Prohibited allocation of securities in an S Corporation.'' is corrected to read ''Prohibited allocations of securities in an S Corporation.''.

Guy R. Traynor,

Federal Register Liaison, Publication and Regulations Branch, Legal Processing Division, Associate Chief Counsel, Procedures and Administration.

[FR Doc. 05–2200 Filed 2–3–05; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7868–5]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule; notice of intent to delete the Southern Maryland Wood Treating Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region III is issuing a notice of intent to delete the Southern Maryland Wood Treating Superfund Site (Site) located in Hollywood, Maryland from the National Priorities List (NPL) and requests public comments on this notice of intent. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), is found at Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the State of Maryland, through the Maryland Department of the Environment (MDE), have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under CERCLA.

In the ''Rules and Regulations'' section of today's **Federal Register**, EPA is publishing a direct final rule of deletion of the Southern Maryland Wood Treating Site without prior notice of intent to delete because EPA views this as a noncontroversial deletion and anticipates no adverse comment. EPA has explained its reasons for this deletion in the direct final rule of deletion. If EPA receives no adverse comment(s) on this notice of intent to delete or the direct final rule of deletion, EPA will not take further action. If EPA receives adverse comment(s), EPA will withdraw the direct final rule of deletion and it will not take effect. EPA will, as appropriate, address all public comments in a subsequent final deletion notice based on this notice of intent to delete. EPA will not institute a second comment period on this notice of intent to delete. Any parties interested in commenting must do so at this time. For additional information, see the Direct Final Rule of Deletion which is located in the ''Rules and Regulations'' section of this **Federal Register**.

DATES: Comments concerning this Site must be received by March 7, 2005.

ADDRESSES: Written comments should be addressed to: Robert Sanchez, Remedial Project Manager, U.S. EPA Region III (3HS23), 1650 Arch Street, Philadelphia, PA 19103–2029, (215) 814–3451.

FOR FURTHER INFORMATION CONTACT: Robert Sanchez, Remedial Project Manager, U.S. EPA Region III (3HS23), 1650 Arch Street, Philadelphia, PA 19103–2029, (215) 814–3451 or 1–800–553–2509.

SUPPLEMENTARY INFORMATION: For additional information, see the Direct Final Notice of Deletion which is located in the ''Rules and Regulations'' section of this **Federal Register**.

Information Repositories: Repositories have been established to provide detailed information concerning this decision at the following addresses: U.S. EPA Region III, Regional Center for Environmental Information (RCEI), 1650 Arch Street (2nd Floor), Philadelphia, PA 19103–2029, (215) 814–5254, Monday through Friday, 8 a.m. to 5 p.m.; and in Maryland at the St. Mary's County Library, 23250 Hollywood Road, Leonardtown, MD 20650 (301) 475–2846, Monday through Friday, 8 a.m. to 4 p.m.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: January 26, 2005.

Richard J. Kampf,

Acting Regional Administrator, Region III.

[FR Doc. 05–2059 Filed 2–3–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–P–7669]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed Base (1% annual-chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate has resolved any appeals resulting from this notification.

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

Source of flooding and location of referenced elevation	♦Elevation in feet (NGVD) *Elevation in feet (NGVD)		Communities affected
	Existing	Modified	
Cobb Creek:			
At the confluence with Florida Creek	None	♦1,099	Lac Qui Parle (Unincorporated Areas).
Approximately 7,850 feet upstream of County Road 50	None	♦1,237	
County Ditch No. 5:			
At the confluence with West Branch Lac Qui Parle River	None	♦1,096	Lac Qui Parle (Unincorporated Areas).
At the western county boundary	None	♦1,140	
Florida Creek:			
At the confluence with West Branch Lac Qui Parle River	None	♦1,094	Lac Qui Parle (Unincorporated Areas).
Approximately 2,300 feet upstream of the southern county boundary.	None	♦1,181	
Florida Creek Tributary:			
At the confluence with Florida Creek	None	♦1,137	Lac Qui Parle (Unincorporated Areas).
At the southern county boundary	None	♦1,208	
Judicial Ditch No. 4:			
At the confluence with West Branch Lac Qui Parle River	♦1,044	♦1,045	City of Dawson, Lac Qui Parle (Unincorporated Areas).
Just upstream of Ninth Street	♦1,044	♦1,045	
Lac Qui Parle River:			
Approximately 350 feet downstream of County Road 20	None	♦ 963	City of Dawson, Lac Qui Parle (Unincorporated Areas).
At the southern county boundary	None	♦1,093	
Lazarus Creek:			
Approximately 9,660 feet downstream of U.S. Interstate 75	None	♦1,105	Lac Qui Parle (Unincorporated Areas).
Approximately 12,100 feet upstream of County Road 52 (2nd crossing).	None	♦1,135	
Lost Creek:			
At the confluence with West Branch Lac Qui Parle River	None	♦1,111	Lac Qui Parle (Unincorporated Areas).
At the western county boundary	None	♦1,193	
Minnesota River:			
Approximately 7.4 miles downstream of County Road 18	None	♦ 934	Lac Qui Parle (Unincorporated Areas).
Approximately 6.9 miles upstream of County Road 15	None	♦ 962	
Minnesota River Tailwaters:			

Source of flooding and location of referenced elevation	♦Elevation in feet (NGVD) *Elevation in feet (NGVD)		Communities affected
	Existing	Modified	
At the confluence with Minnesota River	None	♦ 949	Lac Qui Parle (Unincorporated Areas).
Approximately 430 feet upstream of U.S. Interstate 75	None	♦ 950	
North Fork Yellow Bank River:			
At the confluence with Main Fork Yellow Bank River	None	♦1,002	Lac Qui Parle (Unincorporated Areas).
At the western county boundary	None	♦1,036	
Tenmile Creek:			
Approximately 1,800 feet downstream of County Road 2	None	♦1,046	City of Boyd, Lac Qui Parle (Unincorporated Areas).
Tenmile Creek:			
Approximately 9,100 feet upstream of County Road 29	None	♦1,056	City of Boyd, Lac Qui Parle (Unincorporated Areas).
Tributary to South Fork Yellow Bank River:			
At the confluence with South Fork Yellow Bank River	None	♦1,089	City of Nassau, Lac Qui parle (Unincorporated Areas).
At the western county boundary	None	♦1,113	
West Branch Lac Qui Parle River:			
At the confluence with Lac Qui Parle River	♦1,043	♦1,041	City of Dawson, Lac Qui Parle (Unincorporated Areas).
Just upstream of County Road 7	None	♦1,192	
Yellow Bank River (Main and South Forks):			
Approximately 100 feet downstream of County Road 40	None	♦971	Lac Qui Parle (Unincorporated Areas).
Approximately 14,450 feet upstream of County Road 7	None	♦1,123	

City of Boyd:

Maps are available for inspection at City Hall, 117 Third Street, Boyd, Minnesota.

Send comments to The Honorable Vern Lein, Mayor, City of Boyd, City Hall, 117 Third Street, Boyd, Minnesota 56218.

City of Dawson:

Maps are available for inspection at City Hall, 675 Chestnut Street, Dawson, Minnesota.

Send comments to The Honorable Glenn Dunham, Mayor, City of Dawson, City Hall, 675 Chestnut Street, Dawson, Minnesota 56232.

City of Nassau:

Maps are available for inspection at City Hall, 229 Fifth Street, Nassau, Minnesota.

Send comments to The Honorable Linda Wildung, Mayor, City of Nassau, City Hall, 229 Fifth Street, Nassau, Minnesota 56257.

Lac Qui Parle County (Unincorporated Areas):

Maps are available for inspection at Lac Qui Parle County Courthouse, 600 West Sixth Street, Madison, Minnesota.

Send comments to The Honorable Vonderharr, Chairperson, County Commissioners, County Courthouse, 600 West Sixth Street, Madison, Minnesota 56256.

Artichoke Creek:			
Approximately 2,500 feet downstream of 225th Avenue Northwest.	None	*1,072	Swift County (Unincorporated Areas).
Just upstream of 260th Avenue Northwest	None	*1,085	
Chippewa River:			
Just downstream of County Road 75	None	*1,028	City of Benson, Swift County (Unincorporated Areas).
At the confluence of East Branch, Chippewa River	None	*1,036	
Cottonwood Creek:			
Approximately 8,170 feet downstream of County Road 2	None	*991	City of Holloway, Swift County (Unincorporated Areas).
Approximately 4,600 feet upstream of County Road 9	None	*1,020	
County Ditch No. 2:			
At County Route 54	None	*1,006	Swift County (Unincorporated Areas).
County Ditch No. 2:			
Approximately 1,250 feet upstream of County Route 54	None	*1,006	Swift County (Unincorporated Areas).
East Branch Chippewa River:			
At the confluence with the Chippewa River	None	*1,036	City of Benson Swift County (Unincorporated Areas).
Just downstream of State Road 29	None	*1,036	
Judicial Ditch No. 19:			
Approximately 18,250 feet upstream of the confluence with East Branch Chippewa River.	None	*1,040	Swift County (Unincorporated Areas).
Approximately 39,350 feet upstream of the confluence with East Branch Chippewa River.	None	*1,049	
Lake Malachy Outlet:			
Approximately 320 feet above confluence with Lake Malachy	None	*1,035	City of Clontarf Swift County (Unincorporated Areas).
Approximately 100 feet upstream of Grace Avenue	None	*1,043	
Minnesota River:			
At Marsh Lake Dam	*946	*948	Swift County (Unincorporated Areas).

Source of flooding and location of referenced elevation	♦Elevation in feet (NGVD) *Elevation in feet (NGVD)		Communities affected
	Existing	Modified	
Approximately 4,750 feet upstream of March Lake Dam	*946	*948	
Pomme De Terre River:			
Approximately 11,700 feet downstream of the Union Pacific Railroad.	*972	*975	City of Appleton Swift County (Unincorporated Areas).
Pomme De Terre River:			
Approximately 15,800 feet upstream of North Herrington Road ..	None	*1,008	City of Appleton Swift County (Unincorporated Areas).

City of Appleton:

Maps are available for inspection at the City Office, 323 West Schlieman Avenue, Appleton, Minnesota.

Send comments to The Honorable William Fliflet, Mayor, City of Appleton, 323 West Schlieman Avenue, Appleton, Minnesota 56208.

City of Benson:

Maps are available for inspection at City Hall, 1410 Kansas Avenue, Benson, Minnesota.

Send comments to The Honorable Paul Kittleson, Mayor, City of Benson, 1410 Kansas Avenue, Benson, Minnesota 56215.

City of Clontarf:

Maps are available for inspection at City Hall, 221 Clonmel Street, Clontarf, Minnesota.

Send comments to The Honorable Tom Staton, Mayor, City of Clontarf, 221 Clonmel Street, Clontarf, Minnesota 56226.

City of Holloway:

Maps are available for inspection at City Hall, 220 DePue Street, Holloway, Minnesota.

Send comments to The Honorable Merlin Schultz, Mayor, City of Holloway, 220 DePue Street, Holloway, Minnesota 56249.

Swift County (Unincorporated Areas):

Maps are available for inspection at 301 14th Street North, Benson, Minnesota.

Send comments to The Honorable Gary Hendrickx, Chairman, Swift County Board of Commissioners, 222 North Miles Street, Appleton, Minnesota 56208.

Florida Creek:			
At the northern county boundary	None	♦1,175	Yellow Medicine (Unincorporated Areas).
Approximately 50 feet upstream of County Road 14	None	♦1,238	
Florida Creek Tributary:			
Approximately 25 feet downstream of the northern county boundary.	None	♦1,209	Yellow Medicine (Unincorporated Areas).
Approximately 6,100 feet upstream of County Road 14	None	♦1,244	
Lac Qui Parle River:			
At the northern county boundary	None	♦1,093	Yellow Medicine (Unincorporated Areas).
Approximately 6,750 feet upstream of State Highway 68	None	♦1,241	
Lazarus Creek:			
At confluence with Lac Qui Parle River	None	♦1,095	Yellow Medicine (Unincorporated Areas).
Approximately 6,270 feet upstream of County Road E2	None	♦1,258	
Minnesota River:			
Approximately 31,200 feet downstream of State Highway 67	♦873	♦877	Yellow Medicine (Unincorporated Areas) Granite Falls.
Approximately 1,580 feet upstream of U.S. Highway 59/212	♦932	♦934	Upper Sioux Community.
Minnesota River Overflow Channel:			
At the confluence with the Minnesota River	♦894	♦896	Yellow Medicine (Unincorporated Areas) Granite Falls.
Minnesota River Overflow Channel:			
Approximately 890 feet upstream the confluence with the Minnesota River.	♦898	♦899	Yellow Medicine (Unincorporated Areas) Granite Falls.
Tenmile Creek:			
Approximately 113,370 feet upstream of the confluence with Lac Qui Parle River.	None	♦1,056	Yellow Medicine (Unincorporated Areas).
Approximately 117,250 feet upstream of the confluence with Lac Qui Parle River.	None	♦1,056	
Yellow Medicine River:			
Approximately 36,700 feet downstream of County Road 8	None	♦1,058	Yellow Medicine (Unincorporated Areas).
Approximately 3,400 feet upstream of the southern county boundary.	None	♦1,100	

City of Granite Falls:

Maps are available for inspection at City Hall, 885 Prentice Street, Granite Falls, Minnesota.

Send comments to The Honorable David Smiglewski, Mayor, City of Granite Falls, 885 Prentice Street, Granite Falls, Minnesota 56241.

Upper Sioux Community:

Maps are available for inspection at Office of the Tribal Council Secretary/FDPO Administrator, Upper Sioux Community Board of Trustees, Granite Falls, Minnesota.

Send comments to Helen M. Blue-Redner, Tribal Chairman, Upper Sioux Community Board of Trustees, P.O. Box 147, Granite Falls, Minnesota 56241.

Yellow Medicine County:

Source of flooding and location of referenced elevation	♦Elevation in feet (NGVD) *Elevation in feet (NGVD)		Communities affected
	Existing	Modified	

Maps are available for inspection at the Planning and Zoning Office, 1000 10th Avenue, Clarkfield, Minnesota.
Send comments to The Honorable John Chattin, County Administrator, County Administrator's Office, 415 9th Avenue, Granite Falls, Minnesota 56241.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2118 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–P–7667]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed Base (1% annual-chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate has resolved any appeals resulting from this notification.

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

State	City/town/county	Source of flooding	Location	#Depth in feet above ground ♦Elevation in feet (NAVD)	
				Existing	Modified
TX	New Braunfels (City) Comal and Guadalupe Counties.	Blieders Creek (Upper Reach).	Approximately 730 feet downstream of State Highway 46.	None	♦815
			Approximately .52 mile upstream of Horseshoe Trail.	None	♦858
		Comal River/Dry Comal Creek.	At the confluence with the Guadalupe River.	♦604	♦617
			Approximately 1,200 feet upstream of Krueger Canyon Road.	♦663	♦666
		Comal Springs/Blieders Creek.	At the convergence with the New Channel Comal River and Old Channel Comal River.	♦623	♦625
			Approximately .41 mile upstream of River Road.	None	♦673
		Guadalupe River	Approximately .65 mile downstream of the confluence of North Guadalupe Tributary.	♦586	♦598
			Approximately 420 feet upstream of the Union Pacific Railroad.	♦626	♦635
		New Channel Comal River	At the convergence with Dry Comal Creek.	♦618	♦625
			At the divergence from the Old Channel Comal River and Comal Springs.	♦623	♦625
		North Guadalupe Tributary	At the confluence with the Guadalupe River.	♦591	♦602
			Approximately 100 feet upstream of FM 1044/Old Marion Road.	♦679	♦678
		Old Channel Comal River	At the confluence with the Comal River	♦611	♦618
			At the divergence from the New Channel Comal River and Comal Springs.	♦623	♦625
		South Guadalupe Tributary.	At the confluence with the North Guadalupe Tributary.	♦596	♦602
			Approximately 100 feet upstream of FM 1044/Old Marion Road.	♦671	♦672

Maps are available for inspection at the New Braunfels Municipal Building, 424 South Castell Avenue, P.O. Box 311747, New Braunfels, Texas.

Send comments to The Honorable Adam Cork, Mayor, City of New Braunfels, New Braunfels Municipal Building, 424 South Castell Avenue, P.O. Box 311747, New Braunfels, Texas 78131–1745.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2117 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–D–7612]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed Base (1% annual chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed below. The BFEs are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: FEMA proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements.

The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this proposed rule is exempt from the requirements of the Regulatory Flexibility Act because proposed or modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to establish and maintain community eligibility in the NFIP. As a result, a regulatory flexibility analysis has not been prepared.

Regulatory Classification. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) • Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
TENNESSEE Benton County				
Kentucky Lake/Big Sandy River.	Along the northwestern County boundary	None	*375	Town of Big Sandy, County Benton (Unincorporated Areas).
Kentucky Lake/Tennessee River.	Approximately 1.5 miles upstream of I–40	*376	*375	Benton County (Unincorporated Areas).
	At the southern County boundary	*376	*375	
Burnside Creek	Approximately 0.6 mile upstream of East Lake Street	None	*381	City of Camden.
	Approximately 500 feet upstream of Stigall Street	None	*393	
Cane Creek	At the confluence of Charlie Creek	None	*378	City of Camden.
	Approximately 450 feet upstream of Post Oak Avenue	None	*426	
Charlie Creek	At the confluence with Cane Creek	None	*378	City of Camden.
	Approximately 0.2 mile upstream of Mimosa Street	None	*438	
Cypress Creek	Just upstream of Old Route 70	None	*378	City of Camden.
	Approximately 0.8 mile upstream of Old Route 70	None	*383	

Benton County (Unincorporated Areas)

Maps available for inspection at the Benton County Courthouse, 1 East Court Square, Room 102, Camden, Tennessee.

Send comments to The Honorable Jimmy Thornton, Benton County Mayor, 1 East Court Square, Room 102, Camden, Tennessee 38302.

Town of Big Sandy:

Maps available at the Big Sandy Town Hall, 65 Front Street, Big Sandy, Tennessee.

Send comments to The Honorable W.L. Waters, Mayor of the Town of Big Sandy, P.O. Box 176, Big Sandy, Tennessee 38221.

City of Camden:

Maps available for inspection at the Camden City Hall, 110 Highway 641 South, Camden, Tennessee.

Send comments to The Honorable Jim Travis, Mayor of the City of Camden, P.O. Box 779, Camden, Tennessee 38320.

TENNESSEE Hardin County				
Tennessee River	At approximately River Mile Mzrker 160 along the Decatur County line.	*391	*388	City of Crump, City of Saltillo, City of Savannah, Hardin County (Unincorporated Areas).
	Approximately 7.75 miles upstream of Pickwick Dam	*420	*419	
Horse Creek	At the confluence with the Tennessee River	*398	*395	Hardin County (Unincorporated Areas).
	Approximately 3,000 feet upstream of Airport Road	*422	*421	

City of Crump

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) • Elevation in feet (NAVD)		Communities affected
		Existing	Modified	

Maps available for inspection at the Crump City Hall, 3020 Highway 64, Crump, Tennessee.

Send comments to The Honorable Phyllis James, Mayor of the City of Crump, P.O. Box 88, Crump, Tennessee 38327.

Hardin County (Unincorporated Areas)

Maps available for inspection at the Hardin County Courthouse, 465 Main Street, Savannah, Tennessee.

Send comments to The Honorable Kevin Davis, Hardin County Mayor, 465 Main Street, Savannah, Tennessee 38372.

City of Saltillo

Maps available for inspection at the Saltillo City Hall, 160 Oak Street, Saltillo, Tennessee.

Send comments to The Honorable David Willis, Mayor of the City of Saltillo, P.O. Box 7888, Saltillo, Tennessee 38370.

City of Savannah

Maps available for inspection at the Savannah City Hall, 140 Main Street, Savannah, Tennessee.

Send comments to The Honorable Robert Shutt, Mayor of the City of Savannah, 140 Main Street, Savannah, Tennessee 38372.

WEST VIRGINIA Cabell County				
Fudges Creek	Approximately 460 feet upstream of Interstate 64	None	•580	Cabell County (Unincorporated Areas).
	Approximately 1,200 feet north of the intersection of Howells Mill Road and U.S. Route 60.	None	•580	
Lee Creek	Approximately 50 feet downstream of Interstate 64	None	•606	City of Milton.
	Approximately 50 feet upstream of Interstate 64	None	•608	

Cabell County (Unincorporated Areas)

Maps available for inspection at the Cabell County Office of Grants, Planning and Permits, Cabell County Courthouse, Room 314, Huntington, West Virginia.

Send comments to Ms. Nancy Cartmill, President of the Cabell County Commission, 750 Fifth Avenue, Suite 300, Huntington, West Virginia 25701.

City of Milton

Maps available for inspection at the City of Milton Annex Building, 1595 U.S. Route 60 East, Milton, West Virginia.

Send comments to The Honorable Betty Sargent, Mayor of the City of Milton, P.O. Box 98, Milton, West Virginia 25541–0098.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2116 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–D–7604]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed Base (1% annual chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed below. The BFEs are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: FEMA proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are

made final, and for the contents in these buildings.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this proposed rule is exempt from the requirements of the Regulatory Flexibility Act because proposed or modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. As a result, a regulatory flexibility analysis has not been prepared.

Regulatory Classification. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

State	City/town/county	Source of flooding	Location	#Depth in feet above ground Elevation in feet (NGVD) *Elevation in feet (NAVD)	
				Existing	Modified
Massachusetts	Duxbury (Town), Plymouth County.	Massachusetts Bay	Approximately 1,000 feet southwest of the intersection of Plymouth Avenue and Bay Avenue.	*10	*11
			Approximately 250 feet east of the intersection of Plymouth Avenue and Bay Avenue.	*19	*21
		Duxbury Bay/Bluefish River.	Approximately 600 feet west of the intersection of River Lane and Washington Street.	*9	*10
		Massachusetts Bay/Kingston Bay.	Approximately 500 feet southeast of the intersection of Loring Street and Bay Road.	*13	*11
			Approximately 850 feet south of the intersection of Bay Road and Landing Road.	*14	*15
		Duxbury Bay	Approximately 500 feet south of the intersection of Powder Point Avenue and King Caesar Road.	*14	*17
		Massachusetts Bay/Duck Hill River/The Marsh.	Approximately 1,000 feet north of the intersection of St. George Street and Strawberry Lane.	*9	*11

Maps available for inspection at the Duxbury Town Hall, 878 Tremont Street, Duxbury, Massachusetts.

Send comments to Mr. Rocco Longo, Duxbury Town Manager, 878 Tremont Street, Duxbury, Massachusetts 02332.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: January 28, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–2115 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 385, 390 and 395

[Docket No. FMCSA–2004–19608; Formerly FMCSA–1997–2350]

RIN 2126–AA90

Hours of Service of Drivers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of availability in public docket; addendum to the regulatory impact analysis for the hours of service rulemaking; request for comments.

SUMMARY: On January 24, 2005, the Federal Motor Carrier Safety Administration (FMCSA) published in the **Federal Register** (70 FR 3339) a Notice of Proposed Rulemaking (NPRM) regarding hours of service of commercial motor vehicle drivers. In that NPRM, FMCSA announced it is reviewing and reconsidering the regulations on hours of service of drivers published on April 28, 2003, and amended on September 30, 2003. In the docket to this January 24, 2005, NPRM, FMCSA re-filed the same Regulatory Impact Analysis (RIA), or comprehensive analysis of economic benefits and costs of the proposed rule, as was filed in the docket for the April 2003 final rule. However, effective

January 1, 2005, the Office of Management and Budget (OMB) imposed new analytical requirements on Federal agencies regarding the preparation of RIAs for economically significant rulemakings. These new requirements include an uncertainty analysis, or an analysis of the ''degree of uncertainty'' associated with key variables used in the analysis (*i.e.*, the percent of all truck-related crashes where commercial driver fatigue is a factor) and how significantly that uncertainty affects the benefit and cost estimates derived. A primary value of uncertainty analysis is its ability to highlight those key variables where additional data collection (to reduce uncertainty) would most benefit the decision making process.

Additionally, OMB now requires a cost-effectiveness analysis for those rulemakings where improved public health and safety are the primary benefits. The cost effectiveness of a regulatory action is typically measured as a ratio of the change in costs occasioned by the action compared to its positive results (*i.e.*, lives saved). A primary value of cost-effectiveness analysis is its ability to identify regulatory options that achieve the most effective use of the resources available without requiring monetization of all of the relevant benefits or costs. In light of these new requirements, FMCSA has prepared an addendum to the original RIA containing the two supplemental analyses and has made it available in Docket FMCSA–2004–19608.

DATES: Comments must be received by March 10, 2005, which is the end of the comment period announced January 24, 2005, in the NPRM for hours of service (70 FR 3339).

ADDRESSES: You may submit comments identified by DOT DMS Docket Number FMCSA–2004–19608 by any of the following methods. Identify your comments as responding to ''RIA ADDENDUM.'' Do not submit the same comments by more than one method. However, in order to allow effective public participation in this rulemaking before the statutory deadline, we encourage use of the Web site that is listed first below. It will provide the most efficient and timely method of receiving and processing your comments.

- Web site: *http://dms.dot.gov*: Follow the instructions for submitting comments on the DOT electronic 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 20590–0001.
- 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.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number (FMCSA–2004–19608) or Regulatory Identification Number (RIN) for this rulemaking (RIN–2126–AA90). Note that all comments received will be posted without change to *http://dms.dot.gov*, including any personal information provided. Please see the Privacy Act heading for further information.

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.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov*.

Comments received after the comment closing date will be included in the docket and we will consider late comments to the extent practicable. FMCSA may, however, issue a final rule at any time after the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Yager, Hours-of-Service Team, Federal Motor Carrier Safety Administration, 202–366–1425.

SUPPLEMENTARY INFORMATION:

Background

On January 24, 2005, FMCSA published in the **Federal Register** (70 FR 3339) an NPRM regarding hours of service of commercial motor vehicle drivers. In that NPRM, FMCSA announced that it is reviewing and reconsidering the regulations on hours of service of drivers published on April 28, 2003 (68 FR 22456), and amended on September 30, 2003 (68 FR 56208). These regulations were vacated by the U.S. Court of Appeals for the District of Columbia Circuit on July 16, 2004. *Public Citizen* et al. v. *Federal Motor Carrier Safety Administration*, 374 F.3d 1209 (D.C. Cir. 2004). Congress subsequently provided that the 2003 regulations will remain in effect until the effective date of a new final rule addressing the issues raised by the court, or September 30, 2005, whichever occurs first (Section 7(f) of the Surface Transportation Extension Act of 2004, Part V). FMCSA is reconsidering the 2003 regulations to determine what changes may be necessary to be consistent with the holdings and *dicta* of the *Public Citizen* decision. To facilitate discussion, the agency is putting forward the 2003 rule as the ''proposal'' on which public comments are requested.

Accordingly, in the docket of the NPRM published on January 24, 2005, FMCSA has included a Regulatory Impact Analysis (RIA), or comprehensive analysis of economic benefits and costs of the proposed rule (Docket Number FMCSA–1997–2350–23302, refiled as FMCSA–2004–19608–80), which is the same RIA filed in the docket of the April 2003 hours-of-service rulemaking. However, effective January 1, 2005, the Office of Management and Budget (OMB) imposed new analytical requirements on Federal agencies in the preparation of RIAs for economically significant rulemakings (OMB Circular No. A–4, Guidelines for the Conduct of Regulatory Analysis). These new requirements include: (1) a quantitative analysis of the degree of uncertainty associated with key inputs to the calculation of benefits and costs (henceforth referred to as ''uncertainty analysis''), and (2) a cost-effectiveness analysis (CEA) for major rulemakings for which primary benefits are improved public health and safety. To meet these new requirements, FMCSA has prepared an addendum to the original RIA containing the two supplemental analyses and has made it available in Docket FMCSA–2004–19608. For instructions to access the docket, see the ''Docket'' heading, above.

Uncertainty Analysis

As stated in OMB Circular A–4, ''The precise consequences (benefits and costs) of regulatory options are not always known with certainty,'' and the uncertainty associated with key inputs to a regulatory impact analysis (*i.e.*, the percent of all truck-related crashes where commercial driver fatigue is a factor) has the potential to affect the accuracy of the benefit and cost estimates derived. However, while the

precise consequences of a regulatory option may not be known with certainty, in many cases the probability of their occurrence can be developed. By examining the uncertainty of several key variables used in the analysis (by way of evaluating the probability of their occurrence), analysts and decision makers can become better informed as to which variables most significantly affect the benefit and cost results and where additional information or data collection (to reduce uncertainty) would be most beneficial.

As such, a primary benefit of an uncertainty analysis is that it highlights which variables in the analysis are the most important, and where additional information for given variables would most contribute to the accuracy of results. In the present analysis, FMCSA developed uncertainty distributions for 20 key variables. Examples include (1) the percent of long-haul drivers with ''intense'' schedules (or those drivers in long-haul operations who are fully utilizing the daily and weekly driving limits on a consistent basis), (2) the percentage of hours worked by commercial drivers in excess of allowed hours, and (3) the percent of all truck-related crashes where commercial driver fatigue was determined to be a factor. A complete list of the variables examined is included in the Addendum filed in the docket. It should be noted here that the original RIA examined the economic impacts of the 2003 final rule from two sets of baseline assumptions: the first, termed the ''Current Rules/100%'' option, assumed full compliance by commercial drivers with the pre-2003 HOS rules when estimating the economic impacts of the regulatory change, while the second, termed the ''Status Quo'' option, assumed less than full compliance with the pre-2003 rules prior to estimating economic impacts. However, the uncertainty analysis conducted here was limited only to the ''Status Quo'' (or less than full compliance) baseline assumption, since only under this set of assumptions did the annual costs of the rulemaking rise above the dollar threshold (*i.e.*, greater than $1 billion in annual costs) outlined in OMB Circular A–4 that requires such an analysis. As such, when reporting on the range of possible cost, benefit, and net cost outcomes of this uncertainty analysis, all results are measured relative to the point estimates derived from the original RIA under the ''Status Quo'' baseline assumption.

Regarding total costs of the NPRM, the uncertainty analysis revealed that there was an 80 percent chance that total annual costs of this rulemaking would fall between $1 and $1.5 billion. Under the ''Status Quo'' baseline, the original RIA derived a point estimate of total annual costs equal to $1.3 billion. As such, the distribution of cost results derived from the uncertainty analysis closely tracked the point estimate of costs derived under the original RIA. Regarding total annual benefits of the NPRM, the uncertainty analysis revealed that there is about an 80 percent chance that annual benefits would fall between $0.5 and $0.8 billion. Under the ''Status Quo'' baseline, the original RIA had derived a point estimate of total annual benefits equal to $0.7 billion. Regarding net costs, the uncertainty analysis indicated about an 80 percent chance that net costs of the NPRM would fall between $0.3 and $0.8 billion, and about a five percent chance that net benefits would accrue from implementation of the proposed rule. Under the ''Status Quo'' baseline, the original RIA had derived a point estimate of total net annual costs equal to $0.6 billion.

Cost Effectiveness Analysis

The cost effectiveness of a regulatory action is typically measured as a ratio of the change in costs occasioned by the action compared to its positive results (*i.e.*, lives saved). A primary value of cost-effectiveness analysis is its ability to identify regulatory options that achieve the most effective use of the resources available without requiring monetization of all of the relevant benefits or costs. Regarding the results of the cost effectiveness analysis, the implementation of the NPRM was estimated to result in a total annual cost of $10.8 million for each fatality prevented, and $0.4 million for each injury prevented. It must be noted here that the CEA results presented here will tend to exaggerate the costs of preventing injuries and fatalities, because implementation of the NPRM would not just prevent injuries and fatalities, but would also prevent truck-related crashes limited to property-damage only. Additionally, the rule is expected to result in time savings as a result of the prevention of truck-related crashes. Full details regarding the results of these analyses may be found in Docket FMCSA–2004–19608.

Issued on: February 1, 2005.

Annette M. Sandberg,

Administrator.

[FR Doc. 05–2185 Filed 2–3–05; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List *Ptilagrostis porteri* (Porter feathergrass) as Threatened or Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 90-day petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 90-day finding for a petition to list *Ptilagrostis porteri* (Porter feathergrass) as threatened or endangered under the Endangered Species Act of 1973, as amended (the Act). We find that the petition and additional information in Service files do not present substantial scientific or commercial information indicating that listing this species may be warranted. We will not be initiating a further status review in response to this petition. The public may submit to us any new information that becomes available concerning the status of or threats to the species.

DATES: The finding announced in this document was made on January 28, 2005. New information concerning this species may be submitted for our consideration at any time.

ADDRESSES: Data, information, comments, or questions concerning this petition finding should be submitted to the Western Colorado Supervisor, U.S. Fish and Wildlife Service, Ecological Services Field Office, 764 Horizon Drive, Building B, Grand Junction, Colorado 81506. The petition finding and supporting information are available for public inspection, by appointment, during normal business hours at the above address. The petition and finding are available on our Web site at *http://r6.fws.gov/plants/feathergrass.*

FOR FURTHER INFORMATION CONTACT: Allan R. Pfister, Supervisor, Western Colorado Ecological Services Field Office, U.S. Fish and Wildlife Service (see **ADDRESSES** section) (telephone (970) 243–2778; facsimile (970) 245–6933).

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(A) of the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires that we make a finding on whether a petition to

list, delist, or reclassify a species presents substantial scientific or commercial information to demonstrate that the petitioned action may be warranted. This finding is to be based on all information available to us at the time the finding is made. To the maximum extent practicable, we make this finding within 90 days of the date the petition was received, and notice of the finding must be published promptly in the **Federal Register**.

We received a petition, dated March 5, 2002, to list the plant *Ptilagrostis porteri* (Porter feathergrass) as threatened or endangered within its historic range. The petition was submitted by Jacob Smith, Executive Director of the Center for Native Ecosystems, and by the Colorado Native Plant Society, Joshua Pollock, Southern Rockies Ecosystem Project, and the American Lands Alliance. We received the petition on March 7, 2002. Action on this petition was precluded due to other priority actions and because funding in Fiscal Years 2002 and 2003 was not sufficient to process a preliminary finding. The petitioners filed a 60-day notice of intent to sue on June 26, 2002, alleging that the Service violated the Act by failing to prepare a 90-day petition finding. A lawsuit was filed in the Federal District Court for the District of Arizona on September 17, 2003. An agreement was reached on May 24, 2004, specifying that the Service would submit for publication in the **Federal Register** on or before January 31, 2005, a determination whether the petition presents substantial information indicating that listing may be warranted.

Species Information

Ptilagrostis porteri is a small, perennial bunchgrass with a tuft of fine, narrow basal leaves 2–12 centimeters (cm) (0.8–4.7 inches (in)) long. Stems are 20–35 cm (7.9–13.8 in) tall with single-flowered spikelets in a terminal panicle about 5–10 cm (2–4 in) long. Panicle branches can be closed or open. Awns are 1.5–2 cm (0.6–0.8 in) long, feathery, and bent below the middle.

Ptilagrostis porteri has very specific soil hydration requirements. It grows on the shoulders and sides of elevated hummocks that have formed in peat fens. The hummocks are elevated above the water table, providing a moist but not saturated peat substrate. Most of the species' habitat is classified as rich or extreme-rich calcareous fen. The pH of these fens is high (7.4–8.6) compared to other montane fens, and the peat accumulates at a much slower rate, about 11 cm (4 in) per thousand years (Sanderson and March 1996). Fens are considered a category 1, irreplaceable resource in the Service's Region 6 (Hartmann 1999).

The fens where *P. porteri* grows are found at elevations from 2,800 to 3,400 meters (m) (9,200 to 11,200 feet (ft)) in the north end of South Park and surrounding Tarryall, Mosquito, and Kenosha mountain ranges in Park County, Colorado, about 130 kilometers (km) (80 miles (mi)) southwest of Denver. One small population occurs in neighboring Summit County, and one small outlier population occurs about 56 km (35 mi) to the southeast in El Paso County. Extreme-rich fens with a similar flora are found elsewhere in the United States in only a few locations in Wyoming and California.

Ptilagrostis porteri is the only *Ptilagrostis* species in North America. The Colorado Natural Heritage Program (CNHP) ranks *P. porteri* as imperiled globally (G2) and in the State of Colorado (S2). It was a Federal category 2 candidate species until 1996 when the candidate categories were discontinued (61 FR 64481). It is designated as a sensitive species on the U.S. Forest Service (USFS) Region 2 list for Colorado.

Twenty-two populations of *Ptilagrostis porteri* are recorded with data in the CNHP data system; three additional records have no available information and two historical records have not been relocated. The CNHP has determined that there are 284 hectares (ha) (702 acres (ac)) of occupied habitat, based on field survey maps of the populations recorded in their geographic information system (CNHP 2004). Other estimates from field observations compiled by Johnston (2004) indicate that the total occupied habitat could be 650 ha (1,600 ac). For this finding, we use the acreage determined by CNHP. Available plant inventory records are too inconsistent to provide reliable estimates of population sizes or trends (CNHP 2004, Johnston 2004, and Sanderson 2000).

Fourteen of the 22 known populations are on USFS land, primarily in Pike National Forest. They contain more than 50 percent of the plants on 183 ha (451 ac) of habitat. The remaining 8 populations are in private or mixed ownership, and contain less than 50 percent of the plants on 104 ha (258 ac) of the known habitat (CNHP 2004).

Each *P. porteri* population is ranked by CNHP for quality and viability. Six populations are ranked A (relatively large, intact, defensible and viable). Five A-ranked populations occur on USFS land, covering about 137 ha (338 ac) of occupied habitat; the remaining A-ranked population occupies an estimated 7 ha (18 ac) of private land. Seven populations are ranked B (small but in good condition, or large but disturbed and/or not viable or defensible). Five B-ranked populations occur on 44 ha (108 ac) of USFS land, and one B-ranked population occurs on 54 ha (134 ac) of private land. Eight populations are ranked C (small, in poor condition, possibly not viable). Three C-ranked populations occur on 2 ha (5 ac) of USFS land, three C-ranked populations occur on 36 ha (89 ac) of USFS and private lands, and two C-ranked populations occur on 6 ha (15 ac) of mostly private lands. One population is ranked D (degraded or not viable); it occurs on 0.8 ha (2 ac) of private land (CNHP 2004).

The 13 A- and B-ranked populations occur in 2 separate watersheds (CNHP 2004). Eight populations are in the South Platte Headwaters watershed. They occur along two headwater tributaries flowing down from the rim of South Park on the west and north sides to the South Platte River, one via the Middle Fork of the South Platte and the other one via Tarryall Creek. Five populations are in the Upper South Platte watershed. Within this watershed, the populations are located in two separate drainages. One drainage runs east into the North Fork of the South Platte; the other exits through underground aquifers (von Ahlefeldt 1989). This distribution across two watersheds and four headwater sources reduces the potential impact to the total population that may result from one water project.

Conservation Status

Pursuant to section 4(a) of the ESA, we may list a species of a plant taxon on the basis of any one of the following factors—(A) Present or threatened destruction, modification, or curtailment of habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) inadequacy of existing regulatory mechanisms; or (E) other manmade or natural factors affecting its continued existence. The petitioners cite threats under factors A, D, and E. The petitioners did not mention any threats due to overutilization (factor B). This grass is not easily harvested for hay, nor is it currently of commercial or horticultural interest. Therefore, overutilization is not considered to be a threat to this species. The petitioners likewise did not cite any threats due to disease or predation (factor C). Predation from grazing is not considered to be a threat to the species because it is not known to be palatable to

livestock, and no diseases or pests are known to have any effect on the species (Johnston 2004; von Ahlefeldt 1989; CNHP 2004). Therefore, disease and predation are not considered to be threats to this species.

In regard to factor A (The Present or Threatened Destruction, Modification, or Curtailment of the Species' Habitat or Range), the petition states that *Ptilagrostis porteri* habitat is threatened by: (1) Water diversions and other hydrological alterations; (2) peat mining and other mining; (3) residential development; (4) livestock grazing; (5) motorized vehicle use; (6) hiking and other non-motorized recreation; and (7) beaver activity.

Potential impacts to the moisture regime for *Ptilagrostis porteri* arise from water projects that would draw down the ground water level and projects that would divert surface water from wetlands and irrigated agricultural lands. The water is purchased by municipalities in the Denver Metropolitan area. The South Park Conjunctive Use Project proposal, cited by the petitioners and active at the time of the petition, would have drawn water from creeks upstream of *P. porteri* populations and from the water table under the wetlands in South Park to supply the city of Aurora in the Denver Metro area with 2,500 hectare-meters (ha-m) (20,000 acre-feet (ac-ft)) of water per year. Water was to be delivered as stream flow in a main tributary creek to the South Platte River (U.S. Geological Survey 2002). The project would have impacted two of the four major drainages where high-quality *P. porteri* populations are found, and may, therefore, have constituted a threat to the species. Lowering the water table in the fen habitat would create conditions too dry for *P. porteri,* whereas construction of recharge reservoirs could over-water the microhabitat for *P.* porteri and could destroy the fen vegetation community. Petitioners state that the project threatened to severely impact 50 to 75 percent of the total habitat occupied by *P. porteri,* based on an assessment by Sanderson (2000).

The South Park Conjunctive Use Project proposal was rejected in District Court for Water Division No. 1 in 1998 in favor of the plaintiff, the Park County Water Preservation Coalition, based on augmentation modeling that showed that available water was insufficient. The Colorado Supreme Court rejected an appeal after the date this listing petition was submitted (Colorado Bar Association 2002). No other major water draw-down projects are currently being proposed in Park County (G. Nichols 2004, Eiseman 2004).

The City of Aurora recently purchased 900 ha-m (7,000 ac-ft) of water per year from an existing City of Thornton project that has been diverting water from 11 South Park ranches for about 20 years (McHugh 2004). There are no available data to indicate whether *Ptilagrostis porteri* habitat has been impacted by this ongoing diversion. The City of Centennial in the metropolitan Denver area has purchased surface water from another ranch that has a 35-ha (86-ac) C-ranked population of *P. porteri*. Two other populations described by the petitioners have been ditched and partially drained in the past. Both of these populations are ranked C because they are small, but the remaining habitat still has a water level sufficient to support the species (CNHP 2004). The town of Fairplay is no longer depending on Beaver Creek water that flows through two *P. porteri* populations; they are now using well water (G. Nichols 2004).

Conservation easement agreements including water rights have recently been completed for three private ranches as part of the South Park Basin Legacy Project. Completed easements now protect a 7-ha (18-ac) A-ranked population and a 0.8-ha (2-ac) D-ranked population (CNHP 2004).

Based on the foregoing, we have concluded that neither the petition nor our files contain substantial information indicating that listing this species may be warranted based on impacts from water diversions and other hydrological alterations.

Petitioners state that there is a moratorium on peat mining in Park County and that the threat is primarily the possibility that the moratorium could be rescinded. Park County regulations allow peat mining to continue if it was permitted before the new policy was adopted, but the County has no record of current activity, nor is there any expectation that new operations will be allowed (Eiseman 2004). Sanderson and March (1996) reported that nearly 20 percent of the total extreme rich fen area in South Park has been permanently lost due to past mining of peat. At least four populations of *Ptilagrostis porteri* have been partially destroyed by peat mining in the past. The remaining portions of these fens survive in good condition because they have subsurface water sources (CNHP 2004). The hypothetical possibility of repeal of protective regulations is not substantial information. Therefore, we conclude that there is not substantial information to indicate that listing the species may be warranted as a consequence of impacts from peat mining.

Placer mining has occurred in the past, and continues at one *Ptilagrostis porteri* location under a USFS permit issued in 1993. The permit covers small-scale recreational mining, comprising about 30 dredging days per year and other activities by about 20 people on weekends and 4 people on weekdays between May and October. A draft Biological Evaluation by the USFS in 2000 (Howard 2000) found no effect to sensitive plant species, although *P. porteri* is known to occur within the project area. The petition and our files do not contain substantial information indicating that placer mining might be a threat to the species.

Petitioners state that residential development alters local hydrology and removes wetland habitat by infilling and, therefore, is a threat to *Ptilagrostis porteri*. Based on private land ownership (CNHP 2004), about 7 of the 22 populations may be vulnerable to this threat; 2 of the 7 have recently been placed in conservation easements. These populations are located in the South Platte Headwaters watershed in 2 of the 4 main drainage systems that support the species. More new residential development has occurred in South Park in the last 5 years than in the 20 years from 1980 to 2000 (G. Nichols 2004). There are 4 centers of new residential development in South Park along Sacramento Creek and the Middle Fork of the South Platte, at Warm Springs Ranch and in the Silver Hills area, all of which are close to populations of *P. porteri*. No substantial information is provided in the petition or available in our files on actual impacts of the existing developments on nearby wetlands. Although there are potential cumulative effects on hydrology and physical structure of the fens, we conclude that there is no substantial information in the petition or our files indicating that these might warrant a listing proposal.

Petitioners state that excessive livestock grazing can cause trampling damage to the fen habitat of *Ptilagrostis porteri*. Grazing pressures have fluctuated historically. Records kept by the USFS for allotments where the largest *P. porteri* populations now occur show that cattle grazing was intense during the 1920s and 1930s. Since 1968, major changes in management have been implemented on the National Forest. Photographs taken in 1939 and 1989 show a dramatic increase in vegetation cover on the fens (von Ahlefeldt 1989), and von Ahlefeldt considered moderate grazing to have a minor impact on *P. porteri* because cattle find it unpalatable and they usually walk between the hummocks

without trampling the plants. Field observations of grazing impacts on *P. porteri* populations over the past 35 years indicate a significant change in grazing management and consequent improvement in the visible condition of vegetation on the fens (CNHP 2004, Johnston 2004). We conclude that neither the petition nor information in our files provides substantial information that grazing is, or is likely to be in the foreseeable future, a threat to the species.

Petitioners state that evidence of off-road vehicle use, including snowmobiles, has been observed at five of the *Ptilagrostis porteri* populations. Similar observations have been recorded by CNHP (2004). There is no available additional documentation of the effects of such impacts on this species or its habitat. Thus we conclude that there is no substantial information to indicate that off-road vehicle use presents a threat to the species.

Petitioners state that trail widening and erosion damage nearby peat bogs. Only minor impacts of this type have been recorded by field surveyors (CNHP 2004). Neither the petition nor our files provides additional information to support the petition's contention that this is a threat to the species. In addition, petitioners cite beaver activity as a potential threat, but state that it is not currently threatening any known populations of *Ptilagrostis porteri*. We have no information to contradict petitioner's statement that beaver activity is not currently threatening any known populations.

In regard to factor D (The Inadequacy of Existing Regulatory Mechanisms), petitioners state that existing regulatory mechanisms are inadequate to ensure protection and recovery for *Ptilagrostis porteri*. The USFS currently manages *P. porteri* as a sensitive species and the habitat is managed as wetlands, in accordance with the USFS Region 2 Policy on protection of fens (Hilliard 2002) and the Watershed Conservation Practices Handbook for Region 2 (2001). The USFS manages about 65 percent of the *P. porteri* habitat. The largest known population, A-ranked by CNHP, is in a Federal Wilderness Area on the Pike National Forest. The management practices under these regulations are discussed under Listing Factor A. Just as we determined that there is not substantial information in the petition or our files that the effects of these regulations may warrant listing, there is also no substantial information that the regulations themselves are inadequate and might warrant a listing.

Petitioners cite the lack of regulations to prevent impacts caused by water diversions as a threat. However, as discussed above, existing law and regulatory mechanisms have resulted in termination of the project cited by petitioners as the greatest threat to the species. The petition does not present, nor do we have, substantial information on other specific threats related to water diversions. Hypothetical possibilities do not constitute substantial scientific information indicating a listing may be warranted. Thus we conclude that the petition has not presented substantial information to indicate that lack of adequate regulatory mechanisms is a threat to the species.

In regard to factor E (Other Natural or Manmade Factors Affecting the Continued Existence of *Ptilagrostis porteri*), the petitioners consider the species to be vulnerable due to the small size of most of its populations. They report that only 9 populations have more than 300 plants, 9 have 100 or fewer plants, and 5 populations have 20 or fewer plants. The CNHP (2004) reports 9 recorded populations smaller than 2 ha (5 ac); 1 is ranked A, 1 is ranked B, 6 are ranked C, and 1 is ranked D (the C and D populations are so ranked primarily because they are small). The size of these small populations refers to the extent of occupied habitat within fens that are more extensive. Therefore, size of the population may not be related to size or condition of the habitat or age or susceptibility to drying out. Size also may not indicate ability to reproduce, because the plants can self-fertilize. Thus available information is not substantial enough to indicate that small numbers of plants or acreage *by itself* pose a threat to this species.

Finding

We have reviewed the petition and its supporting documentation, as well as information in our files and other readily available information. On the basis of this review, we find that the petition does not present substantial information indicating that listing of *Ptilagrostis porteri* may be warranted, nor do we have such information. The petition is based primarily on the threat of habitat destruction by major water draw-down and diversion projects. The major water draw-down project that was imminent at the time of petition submission (2002) is no longer proposed. No water projects are currently planned on Federal land within the species' range. Likewise, substantial information is not available to indicate that the other potential impacts cited by the petitioners rise to a level that threatens the species.

In making this finding we rely on information provided by the petitioners and that readily available to us, and evaluate that information in accordance with 50 CFR 424.14(b). The contents of this finding summarize information included in the petition and information that was available to us at the time of the petition review. Our review for the purposes of a so-called ''90-day'' finding under section 4(b)(3)(A) of the ESA and § 424.14(b) of our regulations is limited to a determination of whether the information in the petition constitutes ''substantial scientific or commercial information'' indicating that listing may be warranted. Available information indicates that the primary threat cited in the petition has been eliminated, and the information relating to it is accordingly no longer applicable. We found that the petition did not provide substantial information on the other threats cited, many of which by the petition's own wording are potential or hypothetical threats rather than existing ones.

References

A complete list of all references cited in this finding is available upon request from the Grand Junction Ecological Services Field Office (*see* **ADDRESSES** section).

Author

The primary author of this document is Ellen Mayo, Grand Junction Ecological Services Field Office, U.S. Fish and Wildlife Service (*see* **ADDRESSES** section).

Authority

The authority for this action is the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: January 28, 2005.

Marshall P. Jones,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 05–2133 Filed 2–3–05; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 70, No. 23
Friday, February 4, 2005

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

Animal and Plant Health Inspection Service

[Docket No. 04–116–2]

Public Meeting; Veterinary Biologics

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: This is the second notice to producers and users of veterinary biological products, and other interested individuals, that we will be holding our 13th public meeting to discuss regulatory and policy issues related to the manufacture, distribution, and use of veterinary biological products. This notice provides information on the agenda as well as the dates, times, and place of the meeting. It also indicates a contact person for obtaining registration forms, lodging information, and copies of the agenda.

DATES: The public meeting will be held Wednesday, April 6, through Friday, April 8, 2005, from 1 p.m. to approximately 5 p.m. on Wednesday, 8 a.m. to approximately 5 p.m. on Thursday, and from 8 a.m. to approximately noon on Friday.

ADDRESSES: The public meeting will be held in the Scheman Conference Center at the Iowa State Center, Ames, IA.

FOR FURTHER INFORMATION CONTACT: Ms. Nicole Ruffcorn, Center for Veterinary Biologics, VS, APHIS, 510 South 17th Street, Suite 104, Ames, IA 50010–8197; phone (515) 232–5785, fax (515) 232–7120; or e-mail: *Nicole.L.Ruffcorn@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** on November 4, 2004 (69 FR 64268, Docket No. 04–116–1), we announced that we would be holding our 13th annual veterinary biologics public meeting and requested that interested persons submit suggestions for agenda topics. Based on the responses and on other considerations, the agenda for the 13th public meeting will include, but is not limited to, the following:

- Bovine spongiform encephalopathy experience, epidemiology aspects, and impact on veterinary biologics;
- Autogenous biologics issues—Industry, user, and regulatory perspectives;
- Veterinary Services program diseases update;
- Veterinary Services polices and processes related to the importation, and transportation of organisms, including select agents;
- Animal Care update;
- Center for Veterinary Biologics regulatory initiatives;
- Technical harmonization issues; and
- Novel technologies.

In addition, updates on current topics of interest in the form of handouts and information stations will include, but not be limited to: Quality Assurance, the Ames Information Management System, document processing (outlines, labels), regulatory updates, shipping permits, the Agriculture Bioterrorism Act of 2002, export certificates, the APHIS Science Fellows Project, Administrative Inspection Reviews, investigations, and the National Centers for Animal Health.

Registration forms, lodging information, and copies of the agenda for the 13th public meeting may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT.** This information is also available on the Internet at *http://www.aphis.usda.gov/vs/cvb.*

The registration deadline is March 26, 2005. A block of hotel rooms has been set aside for this meeting until March 14, 2005. Early reservation of rooms is strongly encouraged.

Done in Washington, DC, this 31st day of January 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–2152 Filed 2–3–05; 8:45 am]

BILLING CODE 3410–34–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed addition to the procurement list; reopening of comment period.

SUMMARY: We are reopening the comment period for the addition to the Procurement List of vegetable oil (domestic) to be furnished to the Federal government by a nonprofit agency employing persons who are blind or have other severe disabilities. In this document, we are clarifying the Federal government requirement for this product. This action will allow interested persons additional time to prepare and submit comments.

DATES: Submit your written comments on this action on or before March 6, 2005.

ADDRESSES: Send your comments on this action to the Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Sheryl D. Kennerly, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *skennerly@jwod.gov.*

SUPPLEMENTARY INFORMATION: On December 10, 2004, we published in the **Federal Register** (69 FR 71777–71778) a notice to add five products and one service to the Procurement List, and to delete one service from the Procurement List. We solicited public comments on these actions for 30 days, ending January 9, 2005.

Since the publication of the notice, we have determined that it is necessary to clarify the Federal government requirement for one of the products to be added: Vegetable Oil (Domestic), 10 percent of U.S. Department of Agriculture (USDA) Requirement, 8945–00–NSH–0002; NPA: Advocacy and Resources Corporation, Cookeville, Tennessee; Contracting Activity: USDA, Farm Service Agency, Washington, DC. At this time the product would be provided exclusively as liquid oil (all

types) in one gallon bottles in a quantity equivalent to 10% of the total government requirement for refined, packaged, vegetable oil for domestic purchases regardless of type or pack style according to CID A–A–20091, Salad Oil, Vegetable. If the Committee approves this addition, USDA will be required to procure the product from the specified nonprofit agency employing persons who are blind or have other severe disabilities.

As a result of this clarification, we are reopening the comment period for this proposed addition to the Procurement List for an additional 30 days from the date of publication of this notice. This will give interested persons additional time to respond. We will also consider all comments we received during the original comment period (December 10, 2004 through January 9, 2005).

Authority: 41 U.S.C. 46–48c.

Dated: February 1, 2005.

G. John Heyer,

General Counsel.

[FR Doc. 05–2202 Filed 2–3–05; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions From Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete services previously furnished by such agencies.

DATES: Comments must be received on or before: March 6, 2005.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Sheryl D. Kennerly, telephone: (703) 603–7740, fax: (703) 603–0655, or e-mail *skennerly@jwod.gov*.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice for each product or service will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

Product/NSN: Can, Friction Top, 8110–00–178–8289, 8110–00–178–8290.
NPA: East Texas Lighthouse for the Blind, Tyler, Texas.
Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, Pennsylvania.

Services

Service Type/Location: Base Supply Center, Portsmouth Naval Shipyard, Portsmouth, New Hampshire.
NPA: Central Association for the Blind & Visually Impaired, Utica, New York.
Contracting Activity: Portsmouth Naval Shipyard, Portsmouth, New Hampshire.
Service Type/Location: Custodial Services, Howard M. Metzenbaum United States Courthouse, 201 West Superior Avenue, Cleveland, Ohio.
NPA: VGS, Inc., Cleveland, Ohio.
Contracting Activity: GSA, PBS–5P, Chicago, Illinois.
Service Type/Location: Custodial Services, Naval Base Ventura County, Ventura, California.
NPA: PRIDE Industries, Inc., Roseville, California.
Contracting Activity: ROICC/Naval Base Ventura County, Point Mugu, California.
Service Type/Location: Janitorial/Custodial, Veterans Affairs Community Based Outpatient Clinic, 4440 Calle Real, Goleta, California.
NPA: Work Training Programs, Inc., Santa Barbara, California.
Contracting Activity: Veteran Integrated Service Network 22, Long Beach, California.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. If approved, the action may result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for deletion from the Procurement List.

End of Certification

The following services are proposed for deletion from the Procurement List:

Services

Service Type/Location: Disassembly of Recorders, U.S. Geological Survey, Hydrologic Instrumentation Facility, Stennis Space Center, Mississippi.
NPA: South Mississippi Regional Center, Long Beach, Mississippi.
Contracting Activity: Department of Interior, USGS, Reston, Virginia.
Service Type/Location: Janitorial/Custodial, U.S. Army Reserve Center, Hoyt Avenue, Binghamton, New York.
NPA: Sheltered Workshop for the Disabled, Inc., Binghamton, New York.
Contracting Activity: Department of the Army, Fort Drum, New York.
Service Type/Location: Rehabilitation of Recorder Covers, U.S. Geological Survey, Bay St. Louis, Mississippi.
NPA: South Mississippi Regional Center, Long Beach, Mississippi.
Contracting Activity: Department of Interior, USGS, Reston, Virginia.

G. John Heyer,

General Counsel.

[FR Doc. 05–2203 Filed 2–3–05; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition and Deletion

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from Procurement List.

SUMMARY: This action adds to the Procurement List products to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List a service previously furnished by such agencies.

EFFECTIVE DATE: March 6, 2005.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Sheryl D. Kennerly, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov.*

SUPPLEMENTARY INFORMATION:

Addition

On December 3, 2004, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (69 F.R. 70223) of proposed additions to the Procurement List.

The following comments pertain to Tape, Pressure Sensitive.

Comments were received from the current contractor for these tapes in response to a Committee request for sales data. The contractor stated that it would experience an initial drop in sales volume, followed by termination of three employees, all with families, immediately. The contractor also noted that it had recently been certified as a participant in the 8(a) program.

The percentage of its sales which the contractor stated it would lose is well below the level which the Committee normally considers to constitute severe adverse impact. The current contract was not awarded under the 8(a) program, so the Committee's policy on refraining from adding products and services on 8(a) contracts to the Procurement List is not applicable in this situation. Taking all these circumstances into account, the Committee considers it appropriate to add the tapes to the Procurement List and create jobs for blind persons, whose unemployment rate is higher than the persons who will likely lose their jobs as a result of the Committee's action.

The following material pertains to item being added to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and impact of the additions on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products to the Government.

2. The action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Products

Product/NSN: Tape, Pressure Sensitive; 7510–00–266–6707; 7510–00–266–6708; 7510–00–266–6710.
NPA: Cincinnati Association for the Blind, Cincinnati, Ohio.
Contracting Activity: Office Supplies & Paper Products Acquisition Center, New York, NY.

Deletion

On December 10, 2004, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (69 FR 71778) of proposed deletion to the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the service listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service deleted from the Procurement List.

End of Certification

Accordingly, the following service is deleted from the Procurement List:

Service

Service Type/Location: Food Service Attendant; Mississippi Air National Guard; Building 129, Dining Facility, Jackson, Mississippi.
NPA: Goodwill Industries of Mississippi, Inc., Ridgeland, Mississippi.
Contracting Activity: Mississippi Air National Guard, Jackson, Mississippi.

G. John Heyer,

General Counsel.

[FR Doc. 05–2204 Filed 2–3–05; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

A–357–812

Honey from Argentina: Initiation of New Shipper Antidumping Duty Review

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

ACTION: Initiation of New Shipper Antidumping Duty Reviews.

EFFECTIVE DATE: February 4, 2005.

FOR FURTHER INFORMATION CONTACT: David Cordell or Robert James at (202) 482–0408 or (202) 482–0469, respectively; AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

The Department received a timely request from El Mana S.A. (El Mana), in accordance with 19 CFR 351.214 (c), for a new shipper review of the antidumping duty order on honey from Argentina. *See Notice of Antidumping Duty Order: Honey from Argentina*, 66 FR 63672 (December 10, 2001). El Mana

identified itself as the exporter of subject merchandise produced by its supplier Federacion de Centros Juveniles Agrarios Cooperativistas Zona SanCor.

As required by 19 CFR 351.214(b)(2)(i), (ii), and (iii)(A), El Mana certified it did not export honey to the United States during the period of investigation (POI), and that it has never been affiliated with any exporter or producer which exported honey during the POI. We note El Mana submitted the volume and date of the first sale to an unaffiliated customer in the United States, and did not submit documentation establishing the date the merchandise was first entered for consumption in the United States. Our inquires and Customs run queries with U.S. Customs and Border Protection (CBP) show that the shipment entered the United States shortly after the anniversary month.

Under section 351.214(f)(2)(ii) of the Department's regulations, when the sale of the subject merchandise occurs within the Period of Review (POR), but the entry occurs after the normal POR, the POR may be extended unless it would be likely to prevent the completion of the review within the time limits set by the Department's regulations. The preamble to the Department's regulations state that both the entry and the sale should occur during the POR, and that under ''appropriate'' circumstances the Department has the flexibility to extend the POR. *See Antidumping Duties; Countervailing Duties; Final Rule, 62 FR 27296*, 27319 (May 19, 1997). In this instance, El Mana's shipment entered in the month following the end of the POR. The Department does not find that this delay prevents the completion of the review within the time limits set by the Department's regulations.

Scope

The merchandise under review is honey from the Argentina. The products covered are natural honey, artificial honey containing more than 50 percent natural honey by weight, preparations of natural honey containing more than 50 percent natural honey by weight, and flavored honey. The subject merchandise includes all grades and colors of honey whether in liquid, creamed, comb, cut comb, or chunk form, and whether packaged for retail or in bulk form. The merchandise under review is currently classifiable under item 0409.00.00, 1702.90.90, and 2106.90.99 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise under review is dispositive.

Initiation of Review

In accordance with section 751(a)(2)(B) of the Tariff Act of 1930 (the Tariff Act), as amended, and 19 CFR 351.214(d)(1), and based on information on the record, we are initiating a new shipper review for El Mana. *See Memoranda to the File through Richard O. Weible, New Shipper Review Initiation Checklist*, dated January 31, 2005, for El Mana. We intend to issue the preliminary results of this review not later than 180 days after the date on which this review was initiated, and the final results of this review within 90 days after the date on which the preliminary results were issued.

Pursuant to 19 CFR 351.214(g)(1)(i)(A) of the Department's regulations, the POR for a new shipper review initiated in the month immediately following the anniversary month will be the 12–month period immediately preceding the anniversary month. Under section 351.214(f)(2)(ii) of the Department's regulations, when the sale of the subject merchandise occurs within the POR, but the entry occurs after the normal POR, the POR may be extended unless it would be likely to prevent the completion of the review within the time limits set by the Department's regulations. Therefore, the POR for this new shipper review is December 1, 2003 through December 31, 2004. This review will cover sales by El Mana of honey produced by Federacion de Centros Juveniles Agrarios Cooperativistas Zona SanCor.

In accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e), we will instruct CBP to allow, at the option of the importer, the posting, until the completion of the review, of a single entry bond or security in lieu of a cash deposit for certain entries of the merchandise exported by the above–listed companies, *i.e*, El Mana as the exporter and Federacion de Centros Juveniles Agrarios Cooperativistas Zona SanCor as the producer. Thus, we will instruct CBP to limit the bonding option only to entries of subject merchandise exported by El Mana and produced by Federacion de Centros Juveniles Agrarios Cooperativistas Zona SanCor.

Interested parties that need access to proprietary information in this new shipper review should submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305 and 351.306. This initiation and notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.214(d).

Dated: January 31, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–436 Filed 2–3–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Notification of Partial Rescission of Antidumping Duty Administrative Review of Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, from the People's Republic of China

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

EFFECTIVE DATE: February 4, 2005.

FOR FURTHER INFORMATION CONTACT: Salim Bhabhrawala or Eugene Degnan, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone (202) 482–1784 or (202) 482–0414, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2004, the Department of Commerce (''the Department'') published a notice of opportunity to request an administrative review of the antidumping duty order on tapered roller bearings and parts thereof, finished or unfinished (''TRBs''), from the People's Republic of China (''PRC'') for the period June 1, 2003, through May 31, 2004. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 69 FR 30873, (June 1, 2004). On June 30, 2004, The Timken Company (the Petitioner) requested that the Department conduct an administrative review of the antidumping duty order covering TRBs from the PRC for entries of subject merchandise produced and exported by China National Machinery Import & Export Corporation, Chin Jun Industrial Ltd., Luoyang Bearing Corporation (Group), Peer Bearing Company–Changshan (''CPZ''), Shanghai United Bearing Co., Ltd., Weihai Machinery Holding (Group) Company, Ltd., Zhejiang Changshan Bearing (Group) Co., Ltd., Zhejiang Changshan Change Bearing Co., and

Zhejiang Machinery Import & Export Corp. Also on June 30, 2004, Yantai Timken Company Limited (''Yantai'') requested an administrative review of entries of subject merchadise produced by Yantai.

On July 28, 2004, the Department published in the **Federal Register** a notice of the initiation of the antidumping duty administrative reveiw of TRBs from the PRC for the period June 1, 2003, though May 31, 2004. *See Initiation of Antidumping and Contervailing Duty Administrative Reviews and Request for Revocation in Part*, 69 FR 45010 (July 28, 2004) (Initiation Notice). On August 5, 2004, the Department issued antidumping duty questionnaires to all of the above respondents.

On October 22, 2004, the Petitioner withdrew its request for an administrative review of sales and entries of subject merchandise produced and exported by CPZ.

Rescission of the Review

Pursuant to 19 CFR § 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of the initiation notice of the requested review. Based on a timely request by the Petitioner, the only party that made a request for review with respect to CPZ, the Department is rescinding this review with respect to CPZ in accordance with 19 CFR 351.213(d)(1). The Department will continue its review of other exporters/producers as announced in the *Intitiation Notice*. *See* 69 FR 45010.

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsiblity concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notificaiton of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of APO is a sanctionable violation.

This determination is issued in accordance with 19 CFR 351.213(d)(4) and section 777(i)(l) of the Tariff Act of 1930, as amended.

Dated: January 28, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 05–2186 Filed 2–3–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Tapered Roller Bearings, and Parts Thereof, Finished or Unfinished from the People's Republic of China: Extension of Time Limit for the Preliminary Results of Antidumping Duty Administrative Review

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

EFFECTIVE DATE: February 4, 2005.

FOR FURTHER INFORMATION CONTACT: Salim Bhabhrawala or Eugene Degnan, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1784 or (202) 482–0414, respectively.

Background

On July 28, 2004, the Department of Commerce (''the Department'') published in the **Federal Register** a notice of initiation of the antidumping duty administrative review of tapered roller bearings and parts, thereof, finished or unfinished from the People's Republic of China for the period June 1, 2003, through May 31, 2004. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 69 FR 45010 (July 28, 2004). The preliminary results of review are currently due no later than March 2, 2005.

Extension of Time Limit for Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), states that, if it is not practicable to complete the review within the time specified, the administering authority may extend the 245–day period to issue its preliminary results by up to 120 days. Completion of the preliminary results of this review within the 245–day period is not practicable because the Department needs additional time to analyze a significant amount of information pertaining to each company's sales practices, factors of production, corporate relationships, and to review responses to supplemental questionnaires.

Because it is not practicable to complete this review within the time specified under the Act, we are extending the time period for issuing the preliminary results of review by 60 days until May 1, 2005, in accordance with section 751(a)(3)(A) of the Act. The final results continue to be due 120 days after the publication of the preliminary results of review.

Dated: January 28, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–435 Filed 2–3–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 020105E]

Proposed Information Collection; Comment Request; Alaska Saltwater Sport Fishing Economic Survey

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before April 5, 2005.

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 should be directed to Dr. Dan Lew, National Marine Fisheries Service, Alaska Fisheries Science Center, 7600 Sand Point Way NE, Seattle, WA 98115; telephone: (206) 526–4252; fax: (206) 526–6723; e-mail: *dan.lew@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Marine Fisheries Service (NMFS) plans to conduct a survey to collect data for conducting economic analyses of marine sport fishing in Alaska. This survey is necessary to understand the factors that affect the economic value of marine recreational fishing trips and improve estimates of fishing trip value.

The Federal Government is responsible for the management of the

Pacific halibut sport fishery off Alaska, while the State of Alaska manages the salmon sport fisheries (Chinook, Coho, Sockeye, Chum, and Pink), as well as several other saltwater sport fisheries. The survey's scope covers marine sport fishing for Pacific halibut, salmon, and other popular marine sport species in Alaska (e.g., lingcod and rockfish). The data collected from the survey will be used to estimate the value of marine fishing to anglers and to analyze how the type of fish caught, catch rates, and fishery regulations affect fishing values and anglers' decisions to participate in Alaska marine fishing activities.

The economic information provided from the survey will help inform fishery managers about the economic values of Alaska marine sport fisheries and the changes to participation in these fisheries with proposed regulations.

II. Method of Collection

The data will be collected through a mail survey. A random sample of sport anglers who have fished in Alaska will receive an initial questionnaire. In subsequent weeks, a reminder postcard and a second questionnaire will be mailed to respondents who have not completed and returned the survey. Those not responding to the second full mailing will be contacted by telephone and asked to complete and return the questionnaire.

III. Data

OMB Number: None.

Form Number: None.

Type of Review: Regular submission

Affected Public: Individuals or households.

Estimated Number of Respondents: 4,000.

Estimated Time Per Response: 30 minutes.

Estimated Total Annual Burden Hours: 2,000.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 31, 2005.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 05–2192 Filed 2–3–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 020105D]

Proposed Information Collection; Comment Request; Cooperative Game Fish Tagging Report

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before April 5, 2005.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Eric Orbesen, NOAA Southeast Region Science Center, Cooperative Tagging Center, 75 Virginia Beach Drive, Miami, FL 33149 or (305) 361–5253.

SUPPLEMENTARY INFORMATION:

I. Abstract

The cooperative tagging center attempts to determine the migration patterns and other biological information of billfish, tunas, and swordfish. The fish tagging report is provided to the angler with the tags, and he/she fills out the card with the information when a fish is tagged. The card is then mailed back to NMFS where the data is stored.

II. Method of Collection

The tag cards are mailed out to constituents who then fill them out with the appropriate data when they tag a fish and mail the tag card back to our offices.

III. Data

OMB Number: 0648–0247.

Form Number: NOAA form 88–162.

Type of Review: Regular submission.

Affected Public: Individuals or households.

Estimated Number of Respondents: 12,000.

Estimated Time Per Response: 0.3 hours.

Estimated Total Annual Burden Hours: 360.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 27, 2005.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 05–2193 Filed 2–3–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 013105A]

U.S. Climate Change Science Program Synthesis and Assessment Product Prospectuses

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of availability and request for public comments.

SUMMARY: The National Oceanic and Atmospheric Administration publishes this notice to announce the availability of draft Prospectuses for three of the U.S. Climate Change Science Program (CCSP) Synthesis and Assessment Products (Products) for public comment. These draft Prospectuses address the following CCSP Topics:

Product 2.1 Scenarios of Greenhouse Gas Emissions and Atmospheric Concentrations and Review of Integrated Scenario Development and Application;

Product 2.2 North American Carbon Budget and Implications for the Global Carbon Cycle; and

Product 3.1 Climate Models and Their Uses and Limitations: Climate Sensitivity, Feedbacks, and Uncertainties.

After consideration of comments received on the draft Prospectuses, the final Prospectuses along with the comments received will be published on the CCSP web site.

DATES: Comments must be received by March 7, 2005.

ADDRESSES: The draft Prospectuses are posted on the CCSP Program Office web site. The web addresses to access the draft Prospectuses are:

Product 2.1 (emissions scenarios): *www.climatescience.gov/Library/sap/sap2–1/sap2–1prospectus-draft.htm*

Product 2.2 (North American carbon budget): *www.climatescience.gov/Library/sap/sap2–2/sap2–2prospectus-draft.htm*

Product 3.1 (climate models): *www.climatescience.gov/Library/sap/sap3–1/sap3–1prospectus-draft.htm.*

Detailed instructions for making comments on the draft Prospectuses are provided with each Prospectus. Comments should be prepared in accordance with these instructions.

FOR FURTHER INFORMATION CONTACT: Richard H. Moss, Ph.D., Director, Climate Change Science Program Office (202) 419–3476.

SUPPLEMENTARY INFORMATION: The CCSP was established by the President in 2002 to coordinate and integrate scientific research on global change and climate change sponsored by 13 participating departments and agencies of the U.S. Government. The CCSP is charged with preparing information resources that support climate-related discussions and decisions, including scientific synthesis and assessment analyses that support evaluation of important policy issues. The Prospectuses addressed by this notice provide a topical overview and describe plans for scoping, drafting, reviewing, producing, and disseminating three of 21 final synthesis and assessment Products that will be produced by the CCSP.

Dated: January 31, 2005.

James R. Mahoney,

Assistant Secretary of Commerce for Oceans and Atmosphere, Director, Climate Change Science Program.

[FR Doc. 05–2194 Filed 2–3–05; 8:45 am]

BILLING CODE 3510–12–S

DEPARTMENT OF DEFENSE

Suspension of the Price Evaluation Adjustment for Small Disadvantaged Businesses

AGENCY: Department of Defense (DoD).

ACTION: Notice of 1-year suspension of the price evaluation adjustment for small disadvantaged businesses.

SUMMARY: The Director of Defense Procurement and Acquisition Policy has suspended the use of the price evaluation adjustment for small disadvantaged businesses (SDBs) in DoD procurements, as required by 10 U.S.C. 2323(e)(3), because DoD exceeded its 5 percent goal for contract awards to SDBs in fiscal year 2004. The suspension will be in effect for 1 year and will be reevaluated based on the level of DoD contract awards to SDBs achieved in fiscal year 2005.

DATES: *Effective Date:* February 24, 2005.

Applicability Date: This suspension applies to all solicitations issued during the period from February 24, 2005, to February 23, 2006.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Schneider, Defense Procurement and Acquisition Policy, OUSD(AT&L)DPAP(P), 3015 Defense Pentagon, Washington, DC 20301–3015, telephone (703) 614–4840; facsimile (703) 614–1254.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 10 U.S.C. 2323(e), DoD has previously granted SDBs a 10 percent price preference in certain acquisitions. This price preference is implemented in Subpart 19.11 of the Federal Acquisition Regulation. Section 801 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 (Pub. L. 105–261) amended 10 U.S.C. 2323(e)(3) to prohibit DoD from granting such a price preference for a 1-year period following a fiscal year in which DoD achieved the 5 percent goal for contract awards established in 10 U.S.C. 2323(a). Since, in fiscal year 2004, DoD exceeded this 5 percent goal, use of this price preference in DoD acquisitions must be suspended for a 1-year period, from February 24, 2005, to February 23, 2006.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

[FR Doc. 05–2174 Filed 2–3–05; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

[OMB Control Number 0704–0259]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Types of Contracts

AGENCY: Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through June 30, 2005. DoD proposes that OMB extend its approval for use through June 30, 2008.

DATES: DoD will consider all comments received by April 5, 2005.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0259, using any of the following methods:

• *Defense Acquisition Regulations Web site: http://emissary.acq.osd.mil/dar/dfars.nsf/pubcomm.* Follow the instructions for submitting comments.

• *E-mail: dfars@osd.mil.* Include OMB Control Number 0704–0259 in the subject line of the message.

• *Fax:* (703) 602–0350.

• *Mail:* Defense Acquisition Regulations Council, Attn: Robin Schulze, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062.

• *Hand Delivery/Courier:* Defense Acquisition Regulations Council, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202–3402.

All comments received will be posted to *http://emissary.acq.osd.mil/dar/dfars.nsf.*

FOR FURTHER INFORMATION CONTACT: Robin Schulze, (703) 602–0326. The information collection requirements addressed in this notice are available electronically on the World Wide Web at: *http://www.acq.osd.mil/dpap/dfars/index.htm.* Paper copies are available from Robin Schulze, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 216, Types of Contracts, and related clauses at DFARS 252.216–7000, Economic Price Adjustment-Basic Steel, Aluminum, Brass, Bronze, or Copper Mill Products; DFARS 252.216–7001, Economic Price Adjustment-Nonstandard Steel Items, and DFARS 252.216–7003, Economic Price Adjustment-Wage Rates or Material Prices Controlled by a Foreign Government; OMB Control Number 0704–0259.

Needs and Uses: The clauses at DFARS 252.216–7000, 252.216–7001, and 252.216–7003 require contractors with fixed-price economic price adjustment contracts to submit information to the contracting officer regarding changes in established material prices or wage rates. The contracting officer uses this information to make appropriate adjustments to contract prices.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Annual Burden Hours: 1,592.

Number of Respondents: 204.

Responses Per Respondent: Approximately 2.

Annual Responses: 395.

Average Burden Per Response: 4.03 hours.

Frequency: On occasion.

Summary of Information Collection

Each clause requires the contractor to submit certain information that the contracting officer uses to adjust contract prices:

a. Paragraph (c) of the clause at DFARS 252.216–7000 requires the contractor to notify the contracting officer of the amount and effective date of each decrease in any established price. Paragraph (d) of the clause permits the contractor to submit a written request to the contracting officer for an increase in contract price.

b. Paragraph (f)(2) of the clause at DFARS 252.216–7001 requires the contractor to furnish a statement identifying the correctness of the established prices and employee hourly earnings that are relevant to the computation of various indices. Paragraph (f)(3) of the clause requires the contractor to make available all records used in the computation of labor indices upon the request of the contracting officer.

c. Paragraph (b)(1) of the clause at DFARS 252.216–7003 permits the contractor to provide a written request for contract adjustment based on increases in wage rates or material prices that are controlled by a foreign government. Paragraph (c) of the clause requires the contractor to make available its books and records that support a requested change in contract price.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

[FR Doc. 05–2170 Filed 2–3–05; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0059]

Federal Acquisition Regulation; Information Collection; North Carolina Sales Tax Certification

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning North Carolina sales tax certification. The clearance currently expires May 31, 2005.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before April 5, 2005.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (VIR), 1800 F Streets, NW, Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Jerry Olson, Contract Policy Division, GSA (202) 501–3221.

SUPPLEMENTARY INFORMATION:

A. Purpose

The North Carolina Sales and Use Tax Act authorizes counties and incorporated cities and towns to obtain each year from the Commissioner of Revenue of the State of North Carolina a refund of sales and use taxes indirectly paid on building materials, supplies, fixtures, and equipment that become a part of or are annexed to any building or structure in North Carolina. However, to substantiate a refund claim for sales or use taxes paid on purchases of building materials, supplies, fixtures, or equipment by a contractor, the Government must secure from the contractor certified statements setting forth the cost of the property purchased from each vendor and the amount of sales or use taxes paid. Similar certified statements by subcontractors must be obtained by the general contractor and furnished to the Government. The information is used as evidence to establish exemption from State and local taxes.

B. Annual Reporting Burden

Respondents: 424.
Responses Per Respondent: 1.
Annual Responses: 424.
Hours Per Response: .17.
Total Burden Hours: 72.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VIR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0059, North Carolina Sales Tax Certification, in all correspondence.

Dated: January 28, 2005

Julia B. Wise

Acting Director,Contract Policy Division

[FR Doc. 05–2197 Filed 2–3–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0031]

Federal Acquisition Regulation; Information Collection; Contractor Use of Government Supply Sources

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning contractor use of Government supply sources. The clearance currently expires on May 31, 2005.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before April 5, 2005.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (VIR), 1800 F Street, NW, Room 4035, Washington, DC 20405. Please cite OMB Control No.9000–0031, Contractor Use of Government Supply Sources, in all correspondence.

FOR FURTHER INFORMATION CONTACT Linda Nelson, Contract Policy Division, GSA (202) 501–1900.

SUPPLEMENTARY INFORMATION:

A. Purpose

When it is in the best interest of the Government and whensupplies and services are required by a Government contract,contracting officers may authorize contractors to use Governmentsupply sources in performing certain contracts.

The information informs the schedule contractor that theordering contractor is authorized to use this Government supplysource and fills the ordering contractor's order under the termsof the Government contract.

B. Annual Reporting Burden

Respondents: 300.

Responses Per Respondent: 7.

Annual Responses: 2,100.

Hours Per Response: .25.

Total Burden Hours: 525.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VIR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4775. Please cite OMB Control No. 9000–0031, Contractor Use of Government Supply Sources, in all correspondence.

Dated: January 28, 2005

Julia B. Wise

Acting Director, Contract Policy Division.

[FR Doc. 05–2198 Filed 2–3–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0032]

Federal Acquisition Regulation; Information Collection; Contractor Use of Interagency Motor Pool Vehicles

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning contractor use of interagency motor pool vehicles. The clearance currently expires on May 31, 2005.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before April 5, 2005.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (VIR), 1800 F Street, NW, Room 4035, Washington, DC 20405. Please cite OMB Control No.9000–0032, Contractor Use of Interagency Motor Pool Vehicles, in all correspondence.

FOR FURTHER INFORMATION CONTACT Linda Nelson, Contract Policy Division, GSA (202) 501–1900.

SUPPLEMENTARY INFORMATION:

A. Purpose

If it is in the best interest of the Government, the contracting officer may authorize cost-reimbursement contractors to obtain, for official purposes only, interagency motor pool vehicles and related services. Contractors' requests for vehicles must obtain two copies of the agency authorization, the number of vehicles and related services required and period of use, a list of employees who are authorized to request thevehicles, a listing of equipment authorized to be serviced, andbilling instructions and address.

A written statement that the contractor will assume, without the right of reimbursement from the Government, the cost or expense of any use of the motor pool vehicles and services not related to the performance of the contract is necessary before the contracting officer may authorize cost-reimbursement contractors to obtain interagency motor pool vehicles and related services.

The information is used by the Government to determine that it is in the Government's best interest to authorize a cost-reimbursement contractor to obtain, for official purposes only,interagency motor pool vehicles and related services, and to provide those vehicles.

B. Annual Reporting Burden

Respondents: 70.
Responses Per Respondent: 2.
Annual Responses: 140.
Hours Per Response: .5.
Total Burden Hours: 70.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection document from the General Services Administration, FAR Secretariat (VIR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0032, Contractor Use of Interagency Motor Pool Vehicles, in all correspondence.

Dated: January 28, 2005

Julia B. Wise

Acting Director, Contract Policy Division.

[FR Doc. 05–2199 Filed 2–3–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education; Overview Information; Comprehensive School Reform Quality Initiatives Program; Notice Inviting Applications for New Awards

Catalog of Federal Domestic Assistance (CFDA) Number: 84.332B.

Note: This notice describes two separate competitions—one competition for Category 1 grant awards and one competition for Category 2 grant awards. Applicants must specify in their application whether they are applying for Category 1 or Category 2 grant awards.

DATES: *Applications Available:* February 4, 2005.

Notification of Intent To Apply: March 7, 2005.

Deadline for Transmittal of Applications: April 5, 2005.

Deadline for Intergovernmental Review: June 6, 2005.

Eligible Applicants: Public or private organizations that provide educational services to public elementary or secondary schools.

Estimated Available Funds: A total of approximately $12 million for the two categories of grants described in this notice. (Of this amount, approximately $5 million is from the fiscal year FY 2004 Comprehensive School Reform (CSR) Quality Initiatives appropriation and approximately $7 million is from the FY 2005 CSR Quality Initiatives appropriation.)

Contingent upon the availability of funds and the receipt of a sufficient number of high-quality applications, we may make additional awards in FY 2006 from the rank-ordered list of unfunded applications from this competition.

Estimated Range of Awards: Please see the chart (chart) elsewhere in this notice under section II, Award Information.

Estimated Average Size of Awards: See chart.

Estimated Number of Awards: At least one award in each of the two categories described in this notice. Any additional awards will be distributed between Category 1 and Category 2 grants based on the quality of the applications.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the CSR Quality Initiatives program, authorized under section 1608 of the Elementary and Secondary Education Act of 1965, as amended (ESEA), is to provide discretionary grants to support activities that will enhance the State-administered CSR program and to enable schools that have been identified for improvement, corrective action, or restructuring under Part A of Title I of the ESEA to meet their State's definition of adequate yearly progress (AYP).

Under this program, the Secretary awards funds to support two specific categories of activities:

Category 1—The grantee provides technical assistance to States, school districts, and schools in making informed decisions regarding approving or selecting providers of comprehensive school reform, and

Category 2—The grantee supports capacity building for comprehensive school reform providers to expand their work in more schools, ensure quality, and promote financial stability.

The Category 1 and Category 2 competitions announced in this notice are independent competitions. The Department will evaluate and fund the Category 1 and Category 2 applications separately.

Priorities: These priorities are from the notice of final priorities for this program, published elsewhere in this issue of the **Federal Register**.

Absolute Priorities

(1) *Absolute priority applicable to both Category 1 and Category 2 applicants.*

For FY 2004 and FY 2005 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we only consider Category 1 and Category 2 applicants that meet this priority. This priority is:

The grantee will assist local educational agencies (LEAs) in more than one State.

(2) *Absolute priority applicable to Category 1 applicants only.*

For FY 2004 and FY 2005 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we only consider Category 1 applicants that meet this priority. This priority is:

The applicant must demonstrate, in its grant application, that its CSR Quality Initiatives award will be matched with funds from one or more private organizations. For each year that a grantee receives a CSR Quality Initiatives award, the match, including any in-kind contributions, must total at least 10 percent of the award.

Competitive Preference Priorities

(1) *Competitive preference priority applicable to Category 1 applicants only.*

For FY 2004 and FY 2005 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award up to 10 additional points to a Category 1 applicant, depending on

the extent to which the applicant meets this priority. This priority is:

The grantee will provide assistance to States, LEAs, and schools in approving or selecting a comprehensive school reform provider or in developing comprehensive school reforms, for schools that are identified as being in need of improvement, corrective action, or restructuring under section 1116 of the Elementary and Secondary Act of 1965, as amended. The applicant will provide a plan for providing States, LEAs and schools with information tools and technical assistance in such areas as using data to identify the instructional needs of students and to clarify the technical assistance and professional development needs of teachers and administrators.

(2) *Competitive preference priority applicable to Category 2 applicants only.*

For FY 2004 and FY 2005 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award up to 10 additional points to a Category 2 applicant, depending on the extent to which the applicant meets this priority. This priority is:

The applicant will implement activities to develop and field-test specific strategies to: (1) Meet the needs of students who have been traditionally underserved by comprehensive school reform providers, such as students with disabilities and students with limited English proficiency and to integrate those strategies into scientifically research-based comprehensive school reforms, or (2) increase the capacity of comprehensive reform providers to serve students in rural areas. These strategies could be additions or enhancements to existing CSR models or services already being provided.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99; (b) the Notice of Final Priorities for the program published elsewhere in this issue of the **Federal Register**.

Program Authority: 20 U.S.C. 6518.

II. Award Information

Type of Award: Discretionary grant.

Estimated Available Funds: Approximately $12 million.

Contingent upon the availability of funds and the receipt of a sufficient number of high-quality applications, we may make additional awards in FY 2006 from the rank-ordered list of unfunded applications from this competition.

Estimated Range of Awards, Estimated Size of Awards, and Funding Cycle:

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	Estimated Range of Award	Estimated Size of Award
Category 1	$500,000 to $1 million annually, for a total of $1.5 million to $3 million over a 36-month project period.	$750,000 annually, for a total of $2.25 million over a 36-month project period.
Funding Cycle Annual funding cycle with an initial award and up to two continuation awards: We will make an initial award to a successful Category 1 applicant for a twelve-month budget period. Continuation funding for the remainder of the project period (which may be up to 36 months) will be contingent on future Congressional appropriations and the performance of the grantee.		

	Estimated Range of Award	Estimated Size of Award
Category 2	$1 million - $3 million for a project period up to 36 months.	$2 million for a project period up to 36 months.
Funding Cycle One-time award: We will give a successful applicant one award for the full project period from the funds available for this competition. (In other words, Category 2 applicants will not receive an initial award and subsequent continuation awards.)		

Estimated Number of Awards: At least one award under both Category 1 and Category 2. Additional funds will be distributed between Category 1 and Category 2 grants based on the quality of the applications.

BILLING CODE 4001–01–C

Estimated Number of Awards: At least one award under both Category 1 and Category 2. Additional funds will be distributed between Category 1 and Category 2 grants based on the quality of the applications.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. *Eligible Applicants:* Public or private organizations that provide educational services to public elementary or secondary schools.

2. *Cost Sharing or Matching:* The following matching requirement is for Category 1 (technical assistance in making informed decisions) applicants only. For each year that a Category 1 grantee receives a CSR Quality Initiatives award, the match, including any in-kind contributions, must total at least 10 percent of the award. Please refer to the Category 1 absolute priorities for more information.

There is no matching requirement for Category 2 (development and capacity building) applicants.

IV. Application and Submission Information

1. *Address to Request Application Package:* You may obtain an application package for this program via the Internet at the following address: *http://www.ed.gov/programs/qualinits/applicant.html*.

You also may request an application package by mail at: Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone (toll free): 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1–877–576–7734.

You may also contact ED Pubs at its Web site: *http://www.ed.gov/pubs/edpubs.html* or you may contact ED Pubs at its e-mail address: *edpubs@inet.ed.gov*.

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.332B

Individuals with disabilities may obtain a copy of the application package in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed elsewhere in this notice under section VII. Agency Contact.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program. An applicant must indicate whether it is applying for funding from Category 1 or Category 2.

Notification of Intent to Apply: We will be able to develop a more efficient process for reviewing grant applications if we have a better understanding of the number of entities that intend to apply for funding.

Therefore, we strongly encourage each potential applicant to send a notification of its intent to apply for funding to the following address: *compreform@ed.gov*. Please indicate which category the potential applicant intends to apply under. The notification of intent to apply for funding is optional and should not include information regarding the proposed application.

Page Limit: Applicants are strongly encouraged to limit their application to 40 pages.

3. *Submission Dates and Times:*

Applications Available: February 4, 2005.

Notification of Intent to Apply: March 7, 2005.

Deadline for Transmittal of Applications: April 5, 2005.

Applications for grants under this program may be submitted electronically using the Electronic Grant Application System (e-Application) accessible through the Department's e-Grants system, or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or by mail or hand delivery, please refer to section IV. 6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Deadline for Intergovernmental Review: June 6, 2005.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Applications for grants under this program may be submitted electronically or in paper format by mail or hand delivery.

a. *Electronic Submission of Applications.*

If you submit your application to us electronically, you must use e-Application available through the Department's e-Grants system, accessible through the e-Grants portal page at: *http://e-grants.ed.gov*.

While completing your electronic application, you will be entering data online that will be saved into a database. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

- Your participation in e-Application is voluntary.
- You must complete the electronic submission of your grant application by 4:30 p.m., Washington, DC time, on the application deadline date. The e-Application system will not accept an application for this program after 4:30 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.
- The regular hours of operation of the e-Grants Web site are 6 a.m. Monday until 7 p.m. Wednesday; and 6 a.m. Thursday until midnight Saturday, Washington, DC time. Please note that the system is unavailable on Sundays, and between 7 p.m. on Wednesdays and 6 a.m. on Thursdays, Washington, DC time, for maintenance. Any modifications to these hours are posted on the e-Grants Web site.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.
- You must submit all documents electronically, including the Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- Any narrative sections of your application should be attached as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format.
- Prior to submitting your electronic application, you may wish to print a copy of it for your records.
- After you electronically submit your application, you will receive an automatic acknowledgement that will include a PR/Award number (an identifying number unique to your application).
- Within three working days after submitting your electronic application, fax a signed copy of the ED 424 to the Application Control Center after following these steps:

1. Print ED 424 from e-Application.

2. The applicant's Authorizing Representative must sign this form.

3. Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the ED 424.

4. Fax the signed ED 424 to the Application Control Center at (202) 245–6272.

- We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of System Unavailability: If you

are prevented from electronically submitting your application on the application deadline date because the e-Application system is unavailable, we will grant you an extension of one business day in order to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

1. You are a registered user of e-Application and you have initiated an electronic application for this competition; and

2. (a) The e-Application system is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) The e-Application system is unavailable for any period of time between 3:30 p.m. and 4:30 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgement of any system unavailability, you may contact either (1) the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** (see VII. Agency Contact) or (2) the e-Grants help desk at 1–888–336–8930. If the system is down and therefore the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application.

Extensions referred to in this section apply only to the unavailability of the Department's e-Application system. If the e-Application system is available, and, for any reason, you are unable to submit your application electronically or you do not receive an automatic acknowledgement of your submission, you may submit your application in paper format by mail or hand delivery in accordance with the instructions in this notice.

b. *Submission of Paper Applications by Mail.*

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service:

U.S. Department of Education, Application Control Center, Attention: 84.332B, 400 Maryland Avenue, SW., Washington, DC 20202–4260; or

By mail through a commercial carrier:

U.S. Department of Education, Application Control Center—Stop 4260, Attention: 84.332B, 7100 Old Landover Road, Landover, MD 20785–1506.

You must show proof of mailing consisting of one of the following:

1. A legibly dated U.S. Postal Service postmark;

2. A legible mail receipt with the date of mailing stamped by the U.S. Postal Service;

3. A dated shipping label, invoice, or receipt from a commercial carrier; or

4. Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

1. A private metered postmark, or

2. A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: 84.332B, 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department:

1. You must indicate on the envelope and—if not provided by the Department—in Item 4 of the ED 424 the CFDA number—and suffix letter, if any—of the competition under which you are submitting your application.

2. The Application Control Center will mail a grant application receipt acknowledgment to you. If you do not receive the grant application receipt acknowledgement within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Selection Criteria: We will use different selection criteria for the Category 1 and Category 2 applications. These criteria are from the regulations at 34 CFR 75.210 and are listed in the application package.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may also notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as specified by the Secretary in 34 CFR 75.118.

4. *Performance Measures:* Under the Government Performance and Results Act (GPRA), the program objective for the Comprehensive School Reform program is to increase the number of CSR program schools that will be removed from school improvement status under Title I of the ESEA. Specifically for the CSR Quality Initiatives program, one performance indicator and related measure for each category have been developed for evaluating the overall effectiveness of the CSR Quality Initiatives program.

For Category 1 (technical assistance in making informed decisions) projects, the performance indicator is ''the usefulness of products and services developed through technical assistance addressed through a survey of target audience members.'' With respect to this indicator, the measure that the Department will specifically look at is ''the percentage of all products and services that receive target audience ratings for usefulness of high and above.''

For Category 2 (model development and capacity building) projects, the indicator is ''the relevance of the projects funded by this program.'' With respect to this indicator, the performance measure is the ''percentage of new research projects funded by the CSR Quality Initiatives program that are deemed to be of high relevance to education practice.''

All Category 1 and Category 2 grantees will be expected to submit an annual performance report addressing these performance measures. Data from the performance measures are included in the yearly report to Congress, key stakeholders, and the public.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Sheila Sjolseth, U.S. Department of Education, OESE/AITQ, 400 Maryland Ave, SW., FB–6, Room 3W237, Washington, DC 20202–6200. Telephone (202) 260–5619 or by email *compreform@ed.gov* or by Internet at the following Web site: *http://www.ed.gov/programs/qualinits/index.html.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in this section.

VIII. Other Information

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http:// www.gpoaccess.gov/nara/index.html.*

Dated: February 1, 2005.

Raymond Simon,

Assistant Secretary for Elementary and Secondary, Education.

[FR Doc. 05–2225 Filed 2–3–05; 8:45 am]

BILLING CODE 4000–01–C

DEPARTMENT OF EDUCATION

Comprehensive School Reform Quality Initiatives

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of final priorities.

SUMMARY: The Assistant Secretary announces priorities under the Comprehensive School Reform (CSR) Quality Initiatives program. The Assistant Secretary may use one or more of these priorities for competitions for fiscal year (FY) 2004 and subsequent years' funds. These priorities focus on schools that are in need of improvement, corrective action, or restructuring and on student groups that have been traditionally underserved, such as students with disabilities, limited English proficient students, and students in rural areas.

EFFECTIVE DATE: These priorities are effective March 7, 2005.

FOR FURTHER INFORMATION CONTACT: Sheila Sjolseth, U.S. Department of Education, OESE/AITQ, 400 Maryland Ave, SW., FB–6, room 3W237, Washington, DC 20202–6200. Telephone: (202) 260–5619 or by e-mail at *compreform@ed.gov* or by the Internet at the following Web site: *http://www.ed.gov/programs/qualinits/index.html.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: The purpose of the CSR Quality Initiatives program, authorized under section 1608 of the Elementary and Secondary Education Act of 1965, as amended (ESEA), is to provide discretionary grants to support activities that will enhance the State-administered CSR program and to enable schools that have been identified as in need of improvement, corrective action, or restructuring under Part A of Title I of the ESEA to meet their State's definition of adequate yearly progress (AYP). Under this program, the Assistant Secretary awards funds to support two specific categories of activities. Grantees under Category 1 will assist States, local educational agencies (LEAs), and schools in making informed decisions regarding approving or selecting providers of comprehensive school reform or in developing comprehensive school reforms. Category 2 projects will foster the development of comprehensive school reform models and support development of capacity for comprehensive school reform providers to expand their work in more schools and ensure quality.

We published a notice of proposed priorities for this program in the **Federal Register** on December 1, 2004. (69 FR 69898). In the notice we proposed four priorities—two priorities specific to Category 1 applications, one priority specific to Category 2 applications, and one priority for both Category 1 and Category 2 applications. Except for a change in the priority for Category 2 applications to clarify the intent of the priority, and other technical changes, there are no differences between the notice of proposed priorities and this notice of final priorities.

Analysis of Comments and Changes

In response to our invitation in the notice of proposed priorities, one party submitted comments on the proposed priorities. This commenter suggested that there be no matching requirement for Category 1 applicants. However, section 1608(1) of the ESEA requires a match for Category 1 applications, and we believe that a 10 percent match, which may include in-kind contributions, is reasonable. Accordingly, we have not made a change to this matching requirement.

Note: This notice does *not* solicit applications. In any year in which we choose to use one or more of these priorities, we invite applications through a notice in the **Federal Register**. When inviting applications we designate each priority as absolute, competitive preference, or invitational. The effect of each type of priority follows.

Absolute priority: Under an absolute priority we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority we give competitive preference to an application by either (1) awarding additional points, depending on how well or the extent to which the application meets the competitive priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the competitive priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority we are particularly interested in applications that meet the invitational priority. However, we do not give an application that meets the

invitational priority a competitive or absolute preference over other applications (34 CFR 75.105(c)(1)).

Priorities

Priority for Category 1 Applicants

The grantee will provide assistance to States, LEAs, and schools in approving or selecting a comprehensive school reform provider or in developing comprehensive school reforms, for schools that are identified as being in need of improvement, corrective action, or restructuring under section 1116 of the Elementary and Secondary Education Act of 1965, as amended. The applicant will provide a plan for providing States, LEAs and schools with information tools and technical assistance in such areas as using data to identify the instructional needs of students and to clarify the technical assistance and professional development needs of teachers and administrators.

Priority for Category 1 Applicants

The applicant must demonstrate, in its grant application, that its CSR Quality Initiatives award will be matched with funds from one or more private organizations. For each year that a grantee receives a CSR Quality Initiatives award, the match, including any in-kind contributions, must total at least 10 percent of the award.

Priority for Category 2 Applicants

The applicant will implement activities to develop and field-test specific strategies to: (1) Meet the needs of students who have been traditionally underserved by comprehensive reform providers, such as students with disabilities and students with limited English proficiency and to integrate those strategies into scientifically research-based comprehensive school reforms, or (2) increase the capacity of comprehensive reform providers to serve students in rural areas. These strategies could be additions or enhancements to existing CSR models or services already being provided.

Priority for Category 1 and 2 Applicants

The grantee will assist LEAs in more than one State.

Executive Order 12866

This notice of final priorities has been reviewed in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this regulatory action.

The potential costs associated with the notice of final priorities are those resulting from statutory requirements and those we have determined as necessary for administering this program effectively and efficiently to provide the most benefits for the greatest number of students.

In assessing the potential costs and benefits—both quantitative and qualitative—of this notice of final priorities, we have determined that the benefits of the proposed priorities justify the costs.

We have also determined that this regulatory action does not unduly interfere with State, local and tribal governments in the exercise of their governmental functions.

We summarized the costs and benefits in the notice of proposed priorities.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism. The Executive Order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

You may also view this document in text at the following site: *http://www.ed.gov/programs/qualinits/index.html.*

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Program Authority: 20 U.S.C. 6518.

Dated: February 1, 2005.

(Catalog of Federal Domestic Assistance Number 84.322B Comprehensive School Reform—Quality Initiatives)

Raymond Simon,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. E5–438 Filed 2–3–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board; Meeting

AGENCY: National Assessment Governing Board; U.S. Department of Education.

ACTION: Notice of open teleconference meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming teleconference meeting of the Assessment Development Committee of the National Assessment Governing Board. This notice also describes the functions of the Board. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify members of the general public of their opportunity to attend. Individuals who will need special accommodations in order to attend the meeting (*i.e.;* interpreting services, assistive listening devices, materials in alternative format) should notify Munira Mwalimu at 202–357–6938 or at *Munira.Mwalimu@ed.gov* no later than February 10, 2004. We will attempt to meet requests after this date, but cannot guarantee availability of the requested accommodation. The meeting site is accessible to individuals with disabilities.

Date: February 14, 2005.

Time: 3 p.m.–4:30 p.m.

Location: National Assessment Governing Board, 800 North Capitol Street, NW., Suite #825, Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Munira Mwalimu, Operations Officer, National Assessment Governing Board, 800 North Capitol Street, NW., Suite #825, Washington, DC 20002–4233, telephone: (202) 357–6938.

On February 14, 2005, the Assessment Development Committee will hold a teleconference meeting from 3 p.m. to 4:30 p.m. to discuss and take action, on behalf of the National Assessment Governing Board on a concept paper which examines the National Assessment of Educational Progress (NAEP) reading framework in the context of preparedness for college and the workplace. The concept paper was

prepared for the Governing Board under contract with Achieve, Inc.

A transcript of the teleconference, and other related matters which are informative to the public and consistent with the policy of the section 5 U.S.C. 552b(c), will be available to the public within 14 days after the meeting. Records are kept of all Board proceedings and are available for public inspection at the U.S. Department of Education, National Assessment Governing Board, Suite #825, 800 North Capitol Street, NW., Washington, DC from 8:30 a.m. to 5 p.m.

Dated: January 31, 2005.

Charles E. Smith,

Executive Director, National Assessment Governing Board.

[FR Doc. 05–2109 Filed 2–3–05; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF EDUCATION

Meeting of the President's Board of Advisors on Tribal Colleges and Universities

AGENCY: White House Initiative on Tribal Colleges and Universities (WHITCU)—U.S. Department of Education.

ACTION: Notice of Board meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of an upcoming meeting of the President's Board of Advisors on Tribal Colleges and Universities (the Board) and is intended to notify the general public of their opportunity to attend. This notice also describes the functions of the Board. Notice of the Board's meetings is required under Section 10(a)(2) of the Federal Advisory Committee Act and by the Board's charter.

Agenda: The purpose of the meeting will be to further enhance the Board's strategic plan including identifying ways to strengthen institutional viability; explore private-sector funding support; expand and complement Federal education initiatives; employ new and emerging technologies; augment resources to ultimately impact the recruitment and retention of students and faculty; and, assist in implementing the *No Child Left Behind Act of 2001* and meet other high standards of educational achievement within the nation's tribal colleges and universities.

Dates and Time: February 16, 2005, 9 a.m. to 4 p.m. and February 17, 2005, 9 a.m. to 12 noon.

Location: Residence Inn Washington—Capitol, 333 E Street, SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Diane L. Cullo, Executive Director, White House Initiative on Tribal Colleges and Universities, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5W254, Washington, DC 20202. Telephone: (202) 401–0302; Fax: (202) 260–0485.

SUPPLEMENTARY INFORMATION: The Board is established by Executive Order 13270 of July 3, 2002 and Executive Order 13316 of September 17, 2003 to provide advice regarding the progress made by Federal Agencies toward fulfilling the purposes and objectives of the first order. The Board also provides recommendations to the President through the Secretary of Education on ways the Federal government can help tribal colleges: (1) Use long-term development, endowment building and planning to strengthen institutional viability; (2) improve financial management and security, obtain private sector funding support, and expand and complement Federal education initiatives; (3) develop institutional capacity through the use of new and emerging technologies offered by both the Federal and private sectors; (4) enhance physical infrastructure to facilitate more efficient operation and effective recruitment and retention of students and faculty; and (5) help implement the No Child Left Behind Act of 2001 and meet other high standards of educational achievement.

The general public is welcome to attend the February 16–17, 2005 meeting, however, space is limited and is available on a first-come, first-served basis. Individuals who need accommodations for a disability in order to attend the meeting (*i.e.,* interpreting services, assistive listening devices, materials in alternative format) should notify Diane Cullo at (202) 401–0302 no later than February 11, 2005. Every attempt to met requests after this date will be made but cannot be guaranteed availability of the requested accommodation. The meeting site is accessible to individuals with disabilities.

A summary of the activities of the meeting and other related materials that are informative to the public will be available to the public within 14 days after the meeting. Records are kept of all Board proceedings and are available for public inspection at the White House Initiative on Tribal Colleges and Universities, United States Department of Education, 400 Maryland Avenue, SW., Room 5W254, Washington, DC 20202.

Margaret Spellings,

Secretary, U.S. Department of Education.

[FR Doc. 05–2280 Filed 2–3–05; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

[Docket No. EA–171–B]

Application To Export Electric Energy Powerex Corp.

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: Powerex Corp. (Powerex) has applied to renew its authority to transmit electric energy from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before March 7, 2005.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Import/Export (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Steven Mintz (Program Office) 202–586–9506 or Michael Skinker (Program Attorney) 202–586–2793.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated and require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On February 25, 1998, the Office of Fossil Energy (FE) of the Department of Energy (DOE) issued Order No. EA–171 authorizing British Columbia Power Exchange Corporation (BC Power) to transmit electric energy from the United States to Canada as a power marketer. That order was renewed on February 23, 2000, and will expire on February 25, 2005. On October 4, 2000, DOE was notified that BC Power had officially changed its name to Powerex Corporation (Powerex).

On January 7, 2005, FE received an application from Powerex to renew its authorization to transmit electric energy from the United States to Canada for a five-year term. Powerex proposes to arrange for the delivery of those exports over the international transmission facilities owned by Basin Electric Power Cooperative, Bonneville Power Administration, Eastern Maine Electric Cooperative, International Transmission

Company, Joint Owners of the Highgate Project, Long Sault, Inc., Maine Electric Power Company, Maine Public Service Company, Minnesota Power, Inc., Minnkota Power Cooperative, New York Power Authority, Niagara Mohawk Power Corporation, Northern States Power, Vermont Electric Power Company, and Vermont Electric Transmission Company.

The construction of each of the international transmission facilities to be utilized by Powerex, as more fully described in the application, has previously been authorized by a Presidential permit issued pursuant to Executive Order 10485, as amended.

Procedural Matters: Any person desiring to become a party to these proceedings or to be heard by filing comments or protests to this application should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the dates listed above.

Comments on the Powerex application to export electric energy to Canada should be clearly marked with Docket EA–171–B. Additional copies are to be filed directly with Paul W. Fox, Bracewell & Patterson, L.L.P., 111 Congress Avenue, Suite 2300, Austin, TX 78746, and Tracey L. Bradley, Bracewell & Patterson, L.L.P., 2000 K Street, NW., Suite 500, Washington, DC 20006, and Mike MacDougall, Powerex Corp., 666 Burrard Street, Suite 1400, Vancouver, British Columbia, Canada, V6C 2X8.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at *http://www.fe.doe.gov.* Upon reaching the Fossil Energy Home page, select ''Electricity Regulation,'' and then ''Pending Proceedings'' from the options menus.

Issued in Washington, DC, on January 28, 2005.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Fossil Energy.

[FR Doc. 05–2183 Filed 2–3–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Energy Conservation Program for Consumer Products: Publication of the Petition for Waiver of Fujitsu General Limited From the DOE Residential Air Conditioner and Heat Pump Test Procedures (Case No. CAC–010)

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

ACTION: Notice of petition for waiver and solicitation of comments.

SUMMARY: Today's notice publishes a Petition for Waiver from Fujitsu General Limited (Fujitsu). The Fujitsu Petition requests a waiver of the test procedures applicable to residential and commercial package air conditioners and heat pumps. The Department of Energy (DOE) is soliciting comments, data, and information with respect to the Petition for Waiver.

DATES: DOE will accept comments, data, and information not later than March 7, 2005.

ADDRESSES: DOE will accept comments on this Petition, identified by case number CAC–010, and submitted by any of the following methods:

- Mail: Ms. Brenda Edwards-Jones, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121.
- Telephone: (202) 586–2945. Please submit one signed paper original.
- Hand Delivery/Courier: Ms. Brenda Edwards-Jones, U.S. Department of Energy, Building Technologies Program, Room 1J–018, 1000 Independence Avenue, SW., Washington, DC 20585.

Docket: For access to the docket to read copies of public comments received, this notice, and the Petition for Waiver, go to the U.S. Department of Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC, (202) 586–9127, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Please call Ms. Brenda Edwards-Jones at the above telephone number for additional information regarding visiting the Resource Room. Please note: The Department's Freedom of Information Reading Room (formerly Room 1E–190 at the Forrestal Building) is no longer housing rulemaking materials.

FOR FURTHER INFORMATION CONTACT: Dr. Michael G. Raymond, U.S. Department of Energy, Building Technologies Program, Mail Stop EE–2J, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9611; e-mail: *Michael.Raymond.ee.doe.gov*; or Francine Pinto, Esq., or Thomas DePriest, Esq., U.S. Department of Energy, Office of General Counsel, Mail Stop GC–72, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585–0103, (202) 586–9507; e-mail: *Francine.Pinto@hq.doe.gov*, or *Thomas.DePriest@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: Title III of the Energy Policy and Conservation Act (EPCA) sets forth a variety of provisions concerning energy efficiency. Part B of Title III (42 U.S.C. 6291–6309) provides for the ''Energy Conservation Program for Consumer Products other than Automobiles.'' Part C of Title III (42 U.S.C. 6311–6317) provides for an energy efficiency program entitled ''Certain Industrial Equipment,'' which is similar to the program in Part B, and which includes commercial air conditioning equipment, packaged boilers, water heaters, and other types of commercial equipment.

Today's notice involves both residential equipment under Part B, and commercial equipment under Part C. Both Parts specifically provide for definitions, test procedures, labeling provisions, energy conservation standards, and the authority to require information and reports from manufacturers. With respect to test procedures, both Parts generally authorize the Secretary of Energy to prescribe test procedures that are reasonably designed to produce results which reflect energy efficiency, energy use and estimated annual operating costs, and that are not unduly burdensome to conduct. (42 U.S.C. 6293, 6314)

Fujitsu's petition requests a waiver from both the residential and commercial test procedures for its Airstage product, which is sold for both residential and commercial applications.

As noted above, the test procedure for residential products appears at 10 CFR Part 430, Subpart B.

For commercial package air-conditioning and heating equipment, EPCA provides that the test procedures shall be those generally accepted industry testing procedures developed or recognized by the Air-Conditioning and Refrigeration Institute (ARI) or by the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE), as referenced in

ASHRAE/IES Standard 90.1 and in effect on June 30, 1992. (42 U.S.C. 6314(a)(4)(A)) This section also provides for the Secretary of Energy to amend the test procedure for a product if the industry test procedure is amended, unless the Secretary determines that such a modified test procedure does not meet the statutory criteria. (42 U.S.C. 6314(a)(4)(B)) On October 21, 2004, the Department published a direct final rule adopting ARI Standard 210/240–2003 for small commercial package air conditioning and heating equipment ≤65,000 Btu/h. (69 FR 61962)

The test procedures in that direct final rule apply to three-phase products, but the Fujitsu product is single phase for both residential and commercial use. There is no prescribed test procedure for single-phase, small commercial packaged air conditioning and heating equipment, so no test procedure waiver is required for commercial Airstage products. Moreover, Fujitsu's Airstage products are, since they are distributed in commerce, to a significant extent, for personal use or consumption by individuals, properly classified as a consumer product. (42 U.S.C. 6291(1)(B)) Thus, the Fujitsu Airstage products require a waiver only from the Department's residential test procedure, which appears at 10 CFR Part 430, Subpart B.

The Department's regulations contain provisions allowing a person to seek a waiver from the test procedure requirements for covered consumer products. These provisions are set forth in 10 CFR 430.27. The waiver provisions allow the Assistant Secretary for Energy Efficiency and Renewable Energy to waive temporarily test procedures for a particular basic model when a petitioner shows that the basic model contains one or more design characteristics that prevent testing according to the prescribed test procedures, or when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. (10 CFR Sections 430.27 (a)(1)) Waivers generally remain in effect until final test procedure amendments become effective, thereby resolving the problem that is the subject of the waiver.

On June 14, 2004, Fujitsu filed a Petition for Waiver from the test procedures applicable to residential and commercial package air conditioning and heating equipment. In particular, Fujitsu seeks a waiver from the residential test procedure contained in 10 CFR Part 430, Subpart B, Appendix M. As previously discussed, no waiver from the commercial test procedure is required. Fujitsu seeks a waiver from the test procedure for its Airstage variable refrigerant flow system, multi-split air conditioner and heat pump models listed below:

Outdoor unit, Heat pump type:
AOU54U****
51.9 kBtu/hr cooling/54.4 kBtu/hr heating, single phase, 208–230Vac, 60Hz
Outdoor unit, Cooling only type:
AOU54F****
51.9 kBtu/hr cooling, single phase, 208–230Vac, 60Hz
Indoor units:
AR Series, Compact duct type (ceiling/floor standing), ARU 7/9/12/14/18/20/22****
AR Series, Duct type, ARU25/30/36/45****
AS Series, Wall mounted type, ASU7/9/12/14/18/24/30****
AU Series, Compact ceiling cassette type, AUU7/9/12/14/18****
AU Series, Ceiling cassette type, AUU20/25/30/36/45/54****
The * denotes engineering differences in the basic models.

Fujitsu seeks a waiver from the applicable test procedure because, Fujitsu asserts, the current test procedure evaluates its Airstage products in a manner that is not representative of their true energy efficiency. Fujitsu claims that the energy usage of its Airstage systems cannot be representatively measured using the current test procedure for the following reasons:

1. The test procedure provides for testing of a pair of indoor and outdoor assemblies making up a typical split system, but provides no direction about how Airstage units, with more than ten thousand combinations of indoor units, could be evaluated with just one outdoor unit test.

2. The test procedure calls for testing ''matched assemblies,'' but Airstage systems are designed to be used in zoning systems where the capacity of the indoor units does not match the capacity of the outdoor unit.

The Fujitsu petition requests that DOE grant a waiver from the existing test procedure until such time as DOE can develop and adopt a test procedure that properly measures the energy efficiency for this class of products. Fujitsu intends to work with DOE, stakeholders, and ARI to develop the appropriate test procedure.

The Department is publishing Fujitsu's Petition for Waiver in its entirety. The Petition contains no confidential information. The Department solicits comments, data, and information with respect to the Petition. The Department is particularly interested in receiving comments and views of interested parties concerning any alternate test procedures, or modifications to test procedures, which the Department could use to fairly represent the energy efficiency of Fujitsu's Airstage products. Any person submitting written comments must also send a copy of such comments to the petitioner. 10 CFR 430.27(b)(1)(iv).

Issued in Washington, DC, on January 28, 2005.

David K. Garman,

Assistant Secretary, Energy Efficiency and Renewable Energy.

BILLING CODE 6450–01–P

FUJITSU GENERAL LIMITED
1116 Suenaga, Takatsu-ku, Kawasaki 213-8502, Japan
Tel.: +81-44-861-7638 Fax.: +81-44-861-7881, 2

FUJITSU

June 14, 2004

David K. Garman
Assistant Secretary, Energy Efficiency and Renewable Energy
U.S. Department of Energy
1000 Independence Ave, SW, Washington, DC 20585-0121
U.S.A.

Subject: Petition for Waiver of Test Procedure under 10 CFR 430.27 and 10 CFR 431.29

Dear Assistant Secretary Garman:

We, Fujitsu General Limited (FGL) established in Japan, respectfully submit this petition to you for a waiver of the test procedures applicable Central air conditioners and Central air conditioning heat pumps for our "Airstage" products.

Our "Airstage" products are variable refrigerant flow multi-split air conditioners and heat pumps, using DC Inverter scroll compressors with variable capacity and have wide range of application from residential uses to light commercial uses such as small offices and shops.
In accordance with 10 CFR 430.27 and 10 CFR 431.29, we request petitions for waiver and applications for interim waiver because prescribed test procedures evaluate the basic models in a manner so unrepresentative of their true energy consumption characteristics as to provide materially inaccurate comparative data.
Enclosed is our petition for waiver of test procedure for Airstage

If we can provide further information, or if it would be helpful to discuss any of this matter further, please contact Mr. Takaki Katsuragawa, Marketing coordinator & HVAC Sales, Fujitsu General America Inc. 353 Route 46 W., Fairfield, N.J. 07004 U.S.A. Phone (973)575-0380 or undersigned.

Yours very truly,

Masami Kato,
Manager, Safety & Compliance Group
Engineering Support Department
Fujitsu General Limited
1116 Suenaga, Takatsu-ku, Kawasaki 213-8502, Japan
E-mail: kato@fujitsugeneral.co.jp Phone: +81-44-861-7638

Enclosure

Enclosure

Petition for waiver of test procedure applicable to our ''Airstage'', variable refrigerant flow multi-split air conditioners and heat pumps, is as follows;

1. The Design Characteristics

We developed ''Airstage'' in response to the need for a comfortable, more energy

efficient air-conditioning system with simple zoning. This compact 54000BTU/h variable refrigerant flow multi-split system provides economical, comfortable air-conditioning for a wide range of applications both residentially and commercially. It consists of one outdoor unit, using a DC Inverter scroll compressor with variable capacity, mated to multiple indoor units and uses variable refrigerant flow and control systems. Piping connections are made by separation tube and/or header and electronic expansion valve units.

Airstage'' has the capability of connecting a single outdoor unit with up to 8 indoor units selected from 5 chassis types with 29 basic models (listed in item 4 of this enclosure), giving these systems more than ten thousand installation combinations. The operating characteristics allow each indoor unit to have a different set temperature and a different mode of operation (*i.e.* on/off/fan).

The DC Inverter scroll compressor and system controls maintain compressor operation under optimum pressure. To precisely match the performance of the system to the load of the conditioned areas, ''Airstage'' detects information on capacity (refrigerant requirements) in the indoor units and temperature (converted into pressure value) of refrigerant gas fed into the compressor through the refrigerant flow system.

The compressor is capable of reducing its operating capacity to as little as 20% of its rated capacity. Zone diversity enables ''Airstage'' to have a total connected indoor unit capacity of up to 150% of the capacity of the outdoor unit.

2. The Grounds for the Petition

We seek a waiver from the test procedures applicable to central air conditioners and central air conditioning heat pumps under Title III of the Energy Policy and Conservation Act (EPCA), Part B of Title III (42 U.S.C. 6291–6309) Energy Conservation Program for Consumer Products other than Automobiles and 10 CFR 430 Energy Conservation Program for Consumer Products and Part C of Title III (42 U.S.C. 6311–6317) Energy Efficiency of Industrial Equipment and 10 CFR 431 Energy Efficiency Program for Certain Commercial and Industrial Equipment.

In particular, we seek a waiver from the currently applicable test procedures provided in 10 CFR 430. 23 (m) Central Air Conditioners and 10CFR 430.27 Appendix M, Subpart B Uniform Test Method for Measuring the Energy Consumption of Central Air Conditioners for residential uses and ARI 210/240 (1989) and ARI 210/240 (1994) that you intend to adopt for commercial uses.

3. The Specific Requirements Sought To Be Waived and the Need for the Waiver

We seek a waiver from the applicable test procedures for ''Airstage'', because the current test procedures evaluates ''Airstage'' in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. We indicate two reasons and describe the details as follows;

(1) The test procedures provide for testing of a pair of indoor and outdoor assemblies making up a typical split system, but provides no direction about how ''Airstage'', with more than ten thousand combinations of indoor units, could be evaluated with just one outdoor unit test.

The test procedures do not provide for separate testing of indoor and outdoor unit of split systems. Rather, they provide for the indoor and outdoor unit to be tested together. Almost all of the systems covered by test procedures have one outdoor unit matched to one indoor unit.

Typical multi-split central air conditioners and heat pumps systems (a configuration with up to four indoor units and one outdoor unit) are presently tested with all indoor units operating. It is practical for these systems to be tested in this manner because matching of indoor units to the outdoor unit are defined and test can be performed with standard representative combination of outdoor and indoor units. However with ''Airstage'' there is no standard representative combination of outdoor and indoor units for testing.

Airstage products are intended to be used in zoning systems where an outdoor unit can be connected with up to 8 separate indoor units in a zoned system. Moreover, we offer 29 indoor unit models. Each of these indoor unit models is designed to be used with up to 7 other indoor units, which need not be the same models, in combination with a single outdoor unit. Thus, for each ''Airstage'' outdoor unit, there are more than ten thousand possible combinations of indoor units that can be matched in a system configuration.

The current test procedure provides no direction for determining what combinations of outdoor unit and indoor units should be tested in these circumstances. While a test procedure using two or three indoor units whose total capacity matches that of the outdoor unit may be considered, the results will not entirely represent the system's true energy consumption characteristics. Because the test procedure sets a condition to the ratings based on one test combination among more than ten thousand possible combinations, they do not represent all system combinations and consumers may misread true energy consumption if their system configuration differs from that condition.

However, it is unduly burdensome for us to conduct each possible combination and not practical. Thus, the test procedure does not contemplate, and cannot practically be applied to our ''Airstage'' consisting of multiple assemblies that are intended to be used in a very large number of different combinations.

(2) The test procedure calls for testing ''matched assemblies'', but ''Airstage'' is designed to be used in zoning systems where the capacity of the indoor units does not match capacity of the outdoor unit.

Indoor and outdoor coils in split systems are typically balanced and the capacity of the outdoor coil is equivalent to the capacity of the indoor coil. However, with ''Airstage'' the sum of the capacity of the indoor units connected into the system can be as much as 150% of the capacity of the outdoor coil. Such unbalanced combinations of indoor units and outdoor unit are possible because of the zoning characteristics of the system; the use of electronic expansion valves to precisely control refrigerant flow to each indoor unit; and the system intelligence for overall system control. The test procedure designed for matched assemblies does not contemplate or address testing for substantially unbalanced zoning systems.

For these reasons, the existing test procedures evaluate ''Airstage'' in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data.

It is not surprising that the existing test procedures do not address the issues listed above, because variable refrigerant flow multi-split systems are newly developed and recently proposed for use in North American markets. However, without a waiver of the test procedures for variable refrigerant flow multi-split systems like ''Airstage'', we are at a competitive disadvantage in the market.

Customers expect us to provide more energy efficiency products however, the current test procedures cannot be meaningfully applied to ''Airstage'' for the reasons described above. Moreover, if there is an applicable test procedure for a covered product, 42 U.S.C. 6293(c) and 42 U.S.C. 6314(d) of EPCA prohibits a manufacturer from making representations about the energy consumption of the equipment unless the equipment has been tested in accordance with such test procedures and the representation fairly discloses the results of the testing.

Therefore, we are at a disadvantage in our ability to provide information on energy consumption to our customers.

This is particularly counterproductive for the ''Airstage'' because these systems are specifically designed to deliver energy savings for customers.

We will do our best to explain customers that current test procedures evaluate ''Airstage'' in a manner so unrepresentative of its true energy consumption characteristics and we applied you for a waiver of test procedures for ''Airstage''.

4. Identification of the Basic Models

We seek a waiver from the test procedures for ''Airstage'', variable refrigerant flow system multi split air conditioners and heat pumps, listed below;

Outdoor unit, Heat pump type: AOU54U****
15.2kW cooling/16.6kW heating, single phase, 208–230Vac, 60Hz
Outdoor unit, Cooling only type: AOU54F****
15.2kW cooling, single phase, 208–230Vac, 60Hz

Indoor units:
AR Series, Compact duct type (ceiling/floor standing), ARU 7/9/12/14/18/20/22****
AR Series, Duct type, ARU25/30/36/45****,
AS Series, Wall mounted type, ASU7/9/12/14/18/24/30****
AU Series, Compact ceiling cassette type, AUU7/9/12/14/18****
AU Series, Ceiling cassette type, AUU20/25/30/36/45/54****
The * denotes engineering differences in the basic models.

5. Identification of the Manufacturers of All Other Basic Models

Variable refrigerant flow multi split air conditioner and heat pump systems are proposed in the United States by Mitsubishi Electric and Electronics USA Inc. and Samsung Electronics Company, Ltd. However, their application is almost exclusively for commercial or industrial uses and not for residential use. Our ''Airstage'', compact, economical and comfortable air-conditioning and heat pump systems, are developed especially for residential and commercial uses.

As far as we know, Samsung Electronics Company, Ltd might offer residential type.

6. Alternate Test Procedures

As we mentioned in (1) of item 3, two or three indoor units whose total capacity match capacity of outdoor unit may be used for testing, but will not entirely represent the true energy consumption characteristics. Thus, there are no alternative test procedures known to us that could evaluate these products in a representative manner.

Conclusion

We seek a waiver of current test procedures established in 10 CFR 430.23(m) Central Air Conditioners and 10 CFR 430.27 Appendix M to Subpart B Uniform Test Method for Measuring the Energy Consumption of Central Air Conditioners for residential uses and ARI 210/240 (1989) and ARI 210/240 (1994) for commercial uses, because the current test procedures evaluate the basic models in a manner so unrepresentative of their true energy consumption characteristics as to provided materially inaccurate comparative data and would like you to grant a waiver from existing test procedures until a representative test procedure is developed and approved by you.

We will work with stakeholders, U.S. Department of Energy, Air-Conditioning & Refrigeration Institute and others, through the process of developing test procedures suitable for products using variable refrigerant flow systems.

[FR Doc. 05–2184 Filed 2–3–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–159–000]

Cheyenne Plains Gas Pipeline Company, LLC; Notice of Proposed Changes in FERC Gas Tariff

January 27, 2005.

Take notice that on January 24, 2005, Cheyenne Plains Gas Pipeline Company, LLC (Cheyenne Plains) tendered for filing a revised firm Transportation Service Agreement with Oneok Energy Services Company, L.P. to become effective January 24, 2005.

Cheyenne Plains states that the revised FTSA updates a previously approved negotiated rate agreement that applies to service on its pipeline system.

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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–427 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER05–325–000]

Credit Suisse First Boston Energy, LLC; Notice of Issuance of Order

January 27, 2005.

Credit Suisse First Boston Energy, LLC (CSFBE) filed an application for market-based rate authority, with an accompanying tariff. The proposed tariff provides for wholesale sales of energy, capacity and ancillary services at market-based rates. CSFBE also requested waiver of various Commission regulations. In particular, CSFBE requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by CSFBE.

On January 25, 2005, the Commission granted the request for blanket approval under part 34, subject to the following:

Any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by CSFBE should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest, is February 24, 2005.

Absent a request to be heard in opposition by the deadline above, CSFBE is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of CSFBE, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of CSFBE's issuances of securities or assumptions of liability.

Copies of the full text of the Commission's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The

Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E5–421 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER05–222–000]

Diablo Winds, LLC; Notice of Issuance of Order

January 27, 2005.

Diablo Winds, LLC (Diablo) filed an application for market-based rate authority, with an accompanying tariff. The proposed tariff provides for wholesale sales of energy, capacity and ancillary services at market-based rates. Diablo also requested waiver of various Commission regulations. In particular, Diablo requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by Diablo.

On January 21, 2005, the Commission granted the request for blanket approval under part 34, subject to the following:

Any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Diablo should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest, is February 22, 2005.

Absent a request to be heard in opposition by the deadline above, Diablo is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of Diablo, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Diablo's issuances of securities or assumptions of liability.

Copies of the full text of the Commission's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426.

The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E5–420 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–110–004]

El Paso Natural Gas Company; Notice of Compliance Filing

January 27, 2005.

Take notice that on January 21, 2005, El Paso tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1A, the following tariff sheets to become effective March 1 2005:

Third Revised Sheet No. 287A,
Third Revised Sheet No. 354.

El Paso states that the tariff sheets comply with the Commission's December 22 Order addressing El Paso's proposed procedures for re-designating primary point rights.

El Paso states that copies of the filing were served on parties on the official service list in the above-captioned proceeding.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–424 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–160–000]

El Paso Natural Gas Company; Notice of Proposed Changes in FERC Gas Tariff

January 28, 2005.

Take notice that on January 25, 2005, El Paso Natural Gas Company (El Paso) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1A, Original Sheet No. 290B, to become effective February 24, 2005.

El Paso states that the tariff sheet specifies a timeline for the sale of available firm capacity.

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 § 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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–447 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–340–011]

Gulf South Pipeline Company, LP; Notice of Compliance Filing

January 28, 2005.

Take notice that on December 6, 2004, Gulf South Pipeline Company, LP (Gulf South) submitted its one-year report of segmentation activity in accordance with the Commission's Orders approving Gulf South's capacity segmentation issued in this proceeding.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before the date as indicated below. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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 February 4, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–446 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR05–9–000]

Jefferson Island Storage & Hub L.L.C.; Notice of Petition for Rate Approval

January 28, 2005.

Take notice that on January 21, 2005, Jefferson Island Storage & Hub L.L.C. (Jefferson Island) filed a petition for rate approval pursuant to § 284.123(b)(2) of the Commission's Regulations. Jefferson Island requests the Commission to approve a maximum rate of $0.0773 per MMBtu for interruptible transportation service under section 311 of the Natural Gas Policy Act.

Any person desiring to participate in this rate 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, 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 on February 18, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–444 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR05–8–000]

Northwest Natural Gas Company; Notice of Petition for Rate Approval

January 28, 2005.

Take notice that on January 18, 2005, Northwest Natural Gas Company (NW Natural) filed pursuant to sections 284.224 and 284.123(b)(2) of the Commission's regulations, a petition for rate approval requesting that the Commission approve the proposed rates as fair and equitable for firm and interruptible storage and related transportation services performed under section 311 of the Natural Gas Policy Act of 1978 (NGPA). NW Natural proposes an effective date of July 1, 2005.

NW Natural states that it is an Oregon corporation serving retail customers via separate facilities located in the States of Oregon and Washington, and that it is a public utility in Oregon and Washington, subject to the jurisdiction of the Public Utility Commission of Oregon and the Washington Utilities and Transportation Commission. NW Natural further states that it holds a limited jurisdiction blanket certificate under section 284.224 of the Commission's regulations under which it provides firm and interruptible

storage and related transportation services.

Any person desiring to participate in this rate 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, 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 online 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 February 18, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–443 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR05–7–000]

ONEOK WesTex Transmission, L.P.; Notice of Petition for Rate Approval

January 28, 2005.

Take notice that on January 3, 2005, ONEOK WesTex Transmission, L.P. (WesTex) tendered for filing a rate petition seeking to revise rates for interruptible transportation service to be performed on the intrastate transmission facilities of the WesTex System under the blanket certificate issued to WesTex. WesTex's further states that the filing contains a revised Statement of Operating Conditions for the non-rate aspects of transportation on the WesTex System.

Any person desiring to participate in this rate 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, 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 email 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 February 18, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–442 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–51–000]

Ozark Gas Transmission, L.L.C.; Notice of Application

January 28, 2005.

Take notice that on January 19, 2005, Ozark Gas Transmission, L.L.C. (Ozark), 515 Central Park Drive, Oklahoma City, Oklahoma 73105 filed an application in Docket No. CP05–51–000 pursuant to section 7(b) of the Natural Gas Act (NGA), requesting that the Commission issue an Order authorizing Ozark to abandon certain of its certificated facilities located in Haskell, Muskogee and LeFlore Counties in the state of Oklahoma and in Cleburne, Faulkner, Franklin, Logan, Johnson, Sebastian and Pope Counties in the state of Arkansas (the Facilities) by transfer to Ozark Arkansas Gas Gathering, L.L.C. (OAGG). Ozark states that the Facilities consist of approximately 137 miles of 3-inch to 12-inch diameter lateral gathering lines, 12 compressor stations, and 134 well connects. Ozark further requests a Commission determination that the Facilities to be abandoned will be gathering facilities exempt from NGA jurisdiction upon their abandonment by transfer to OAGG, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call (202) 502–3676, or TTY, (202) 502–8659.

Any questions concerning this application should be directed to counsel for Ozark, James F. Bowe, Jr., Dewey Ballantine LLP, at (202) 429–1444 (phone), (202) 429–1579 (fax), or *jbowe@deweyballantine.com.*

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents

filed by the applicant and by all other parties. Unless filing electronically, a party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

Persons who wish to comment only on the environmental review of this project, or in support of or in opposition to this project, should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the applicant. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

Comment Date: February 18, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–448 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–157–000]

Saltville Gas Storage Company L.L.C.; Notice of Negotiated Rate Filing

January 27, 2005.

Take notice that on January 21, 2005, Saltville Gas Storage Company L.L.C. (Saltville) tendered for filing negotiated rate transactions with Virginia Gas Distribution Company, Sequent Energy Management, L.P., the Oak Ridge Utility District, NJR Energy Resources, and Public Service Company of North Carolina, Inc. Saltville states that the purpose of this filing is to implement negotiated rate agreements for services rendered by its Saltville, Virginia gas storage facility.

Saltville requests an effective date of January 1, 2005 for the Service Agreements. In addition, Saltville requests that the Commission grant any authorizations and waivers of the Commission's regulations to the extent necessary to permit the service agreements to be made effective as proposed. Saltville requests an additional period of 30 days in which to complete discussions with its customers and to file its remaining negotiated rate agreements.

Saltville states that copies of the filing were mailed to all affected customers of Saltville 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 email 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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–425 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–480–015]

Texas Eastern Transmission, LP; Notice of Negotiated Rate

January 27, 2005.

Take notice that on January 21, 2005, Texas Eastern Transmission, LP (Texas Eastern) tendered for filing as a part of its FERC Gas Tariff, Seventh Revised Volume No. 1, the following tariff sheets reflecting the negotiated rate for interruptible backhaul transportation service to be rendered to the City of Hamilton, Ohio (Hamilton), effective as set forth in the negotiated rate tariff sheets:

Original Sheet No. 112
Original Sheet No. 113
Sheet Nos. 114–125

Texas Eastern states that the purpose of this filing is to implement the negotiated rate agreement for interruptible backhaul transportation service to be rendered to Hamilton. In addition, Hamilton further states that it has agreed to withdraw its pending complaint in Docket No. RP04–254 effective upon Commission approval of the negotiated rate.

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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–419 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–161–000]

Texas Gas Transmission, LLC; Notice of Annual Cash-Out Report

January 28, 2005.

Take notice that on January 26, 2005, Texas Gas Transmission, LLC (Texas Gas) tendered for filing a report, which compares its cash-out revenues with its cash-out costs incurred for the annual billing period November 1, 2003, through October 31, 2004, in accordance with its tariff. Texas Gas states that there is no rate impact to customers as a result of the filing.

Texas Gas states that copies of the filing have been served upon jurisdictional 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 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: February 4, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–439 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–53–000]

Texas Gas Transmission, LLC; Notice of Application

January 28, 2005.

Take notice that on January 19, 2005, Texas Gas Transmission, LLC (Texas Gas), 3800 Frederica Street, Owensboro, Kentucky 42301, filed an application pursuant to section 7(b) of the Natural Gas Act (NGA) for permission and approval to plug and abandon Well 17041 at its Graham Lake Storage Field in Muhlenburg County, Kentucky.

This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Any questions concerning this request may be directed to Kathy D. Fort, Manager of Certificates and Tariffs, Texas Gas Transmission, LLC, P.O. Box 20008, Owensboro, Kentucky 42304, or call (270) 688–6825.

Texas Gas states that Well 17401 has been operational as a storage well since May 1, 1980, drilled through an underground coal mine. On this basis, Texas Gas has determined that the risks associated with the continued operation of Well 17041 are too great. Texas gas proposes to plug and abandon Well 17401 to address the inherent safety concerns. Texas Gas points out that lateral lines associated with Well 17041 would be abandoned pursuant to Texas Gas's Blanket certificate. Texas Gas asserts that the operational capabilities of the Graham Lake Storage field would not be affected by the abandonment.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street, NE. Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party

status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-filing'' link. The Commission strongly encourages electronic filings.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

Comment Date: February 18, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–440 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–158–000]

Viking Gas Transmission Company; Tariff Filing and Request for Waiver

January 27, 2005.

Take notice that on January 21, 2005, Viking Gas Transmission Company (Viking) tendered for filing to become part of Viking's FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheets to become effective February 20, 2005:

Eighth Revised Sheet No. 12
Third Revised Sheet No. 41B
Fourth Revised Sheet No. 13
Third Revised Sheet No. 15L
Eleventh Revised Sheet No. 48
Second Revised Sheet No. 15M.01
Twelfth Revised Sheet No. 49
Second Revised Sheet No. 15N
Sixth Revised Sheet No. 21
Tenth Revised Sheet No. 77
Sixth Revised Sheet No. 23
Second Revised Sheet No. 87E
First Revised Sheet No. 87H.01

Viking states that this filing is being made to clarify the impact and billing for zero mile transportation transactions in Viking's Tariff and to make certain housekeeping changes.

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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–426 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL04–112–000, et al.]

The Governors, et al.; Electric Rate and Corporate Filings

January 28, 2005.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. The Governors of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont

[Docket No. EL04–112–000]

On January 11, 2005, the Governors of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont (New England Governors) filed a motion to lodge amendments to the Joint Petition for Declaratory Order to Form a New England Regional State Committee, filed on June 25, 2004 in the above-docketed proceeding.

Comment Date: 5 p.m. eastern time on February 7, 2005.

2. Wisconsin Public Service Corporation, WPS Power Development, Inc., WPS Energy Services, Inc.

[Docket Nos. ER95–1528–010 and ER96–1088–035]

Take notice that WPS Resources Corporation (WPSR), on January 24, 2005, tendered for filing its response to the Commission's January 3, 2005 deficiency letter issued in Docket Nos. ER95–1528–008 and ER96–1088–033 regarding a renewal of the market-based rate authority of WPSR's subsidiaries. WPSR states that part of this information was submitted on a confidential basis. In addition, WPSR states that it is submitting a market

power analyses using the footprint of the Midwest System Independent Transmission System, Inc. as a whole.

Comment Date: 5 p.m. eastern time on February 14, 2005.

3. Merrill Lynch Capital Services, Inc.

[Docket No. ER99–830–009]

Take notice that on January 21, 2005, Merrill Lynch Capital Services, Inc. (MLCS) filed a triennial updated market analysis.

MLCS states that copies of the filing were served on the parties listed on the official service list in this proceeding.

Comment Date: 5 p.m. eastern time on February 11, 2005.

4. Entergy Services, Inc.

[Docket No. ER01–2214–005]

Take notice that on January 24, 2005, Entergy Services, Inc., (Entergy) filed a refund report in the above captioned docket relating to Entergy's ancillary services schedules 3–6.

Entergy states that a copy of the refund report has been served on all parties to the service lists in the above-referenced proceedings and State commissions in the Entergy region.

Comment Date: 5 p.m. eastern time on February 14, 2005.

5. Commonwealth Edison Company and Commonwealth Edison Company of Indiana, Inc.; PJM Interconnection, LLC and Commonwealth Edison Company and Commonwealth Edison Company of Indiana, Inc.

[Docket Nos. ER03–1335–003, ER04–367–005]

Take notice that on January 21, 2005, Commonwealth Edison Company and PJM Interconnection, L.L.C. filed a compliance filing pursuant to the Commission's Order issued December 22, 2004 in Docket No. ER03–1335–000, *et al.,* 109 FERC ¶ 61,228.

Comment Date: 5 p.m. eastern time on February 11, 2005.

6. Pacific Gas and Electric Company

[Docket No. ER04–443–005]

Take notice that on January 21, 2005, Pacific Gas and Electric Company (PG&E) tendered for filing revisions to its Transmission Owner Tariff, FERC Electric Tariff, Sixth Revisied Volume No. 5. PG&E states that the revisions are intended to comply with Commission Order Nos. 2003 and 2003–A. PG&E requests that the revisions become effective on the same date as companion filings made by the California Independent System Operator Corporation on January 5, 2005, in compliance with Order No. 2003.

Comment Date: 5 p.m. eastern time on February 11, 2005.

7. Mystic I, LLC; Mystic Development, LLC; Fore River Development, LLC

[Docket Nos. ER04–657–004, ER04–660–004, ER04–659–004]

Take notice that on January 21, 2005, Mystic I, LLC, Mystic Development, LLC and Fore River Development, LLC submitted an amendment to their September 24, 2004 filing, as supplemented on October 1, 2004, of a joint triennial updated market analysis.

Comment Date: 5 p.m. eastern time on February 11, 2005.

8. Midwest Independent Transmission System Operator, Inc.; Public Utilities with Grandfathered Agreements in the Midwest ISO Region

[Docket Nos. ER04–691–019, EL04–104–018]

Take notice that on January 21, 2005, the Midwest Independent Transmission System Operator, Inc. (Midwest ISO) submitted a compliance filing pursuant to the Commission's August 6, 2004 order, *Midwest Independent Transmission System Operator, Inc., et al.,* 108 FERC ¶ 61,163 (2004) and its December 20, 2004 order, *Midwest Independent Transmission System Operator, Inc., et al.,* 109 FERC ¶ 61,285 (2004).

The Midwest ISO states that it has electronically served a copy of this filing, with attachments, upon all Midwest ISO members, member representatives of transmission owners and non-transmission owners, the Midwest ISO advisory committee participants, policy subcommittee participants, as well as all State commissions within the region.

In addition, the Midwest ISO states that the filing has been electronically posted on the Midwest ISO's Web site at *http://www.midwestiso.org* under the heading ''Filings to FERC'' for other interested parties in this matter. The Midwest ISO indicates that it will provide hard copies to any interested party upon request.

Comment Date: 5 p.m. eastern time on February 11, 2005.

9. Milford Power Company, LLC

[Docket No. ER05–163–001]

Take notice that on January 21, 2005, Milford Power Company, LLC (Milford) tendered for filing its responses to the Commission's deficiency letter issued December 22, 2004 regarding Milford's November 1, 2004 filing in Docket No. ER05–163–000.

Comment Date: 5 p.m. eastern time on February 11, 2005.

10. Kansas City Power & Light Company

[Docket No. ER05–177–006]

Take notice that on January 21, 2005, Kansas City Power & Light Company (KCPL) submitted a compliance filing pursuant to the Commission's order issued December 28, 2004 in Docket No. ER05–177–000. KCPL states that this filing pertains to service schedules for the City of Marshall, Missouri.

KCPL states that copies of the filing were served upon the City of Marshall, Missouri as well as the Missouri Public Service Commission and the Kansas State Corporation Commission.

Comment Date: 5 p.m. eastern time on February 11, 2005.

11. Entergy Louisiana, Inc.; Entergy Services, Inc.; Perryville Energy Partners, LLC.

[Docket Nos. ER05–188–001, ER05–189–001, ER05–191–001]

Take notice that on January 21, 2005, Perryville Energy Partners, LLC (PEP), Entergy Services, Inc. (ESI) and Entergy Louisiana, Inc. (ELI) submitted additional information amending the November 5, 2004 filings of PEP in Docket No. ER05–191–000, ESI in Docket No. ER05–189–000 and ELI in Docket No. ER05–188–000 in response to the Commission's deficiency letter issued December 29, 2004 in the above-referenced proceedings.

Comment Date: 5 p.m. eastern time on February 11, 2005.

12. El Paso Electric Company

[Docket No. ER05–201–001]

Take notice that on January 21, 2005, El Paso Electric Company (EPE) submitted a compliance filing pursuant to the Commission's Letter Order issued January 6, 2005 in Docket No. ER05–201–000.

EPE states that a copy of the filing was served on the parties on the official service list for this proceeding, the Public Utility Commission of Texas, the New Mexico Regulatory Commission and the Public Service Company of New Mexico.

Comment Date: 5 p.m. eastern time on February 11, 2005.

13. PacifiCorp

[Docket No. ER05–278–001]

Take notice that on January 24, 2005, PacifiCorp tendered for filing in accordance with 18 CFR 35 of the Commission's rules and regulations an amendment to its filing dated November 29, 2004 under FERC Docket No. ER05–278–000.

PacifiCorp states that copies of this filing were supplied to the Public Utility

Commission of Oregon, the Washington Utilities and Transportation Commission, and NorthWestern Energy.

Comment Date: 5 p.m. eastern time on February 14, 2005.

14. Duke Energy Corporation

[Docket No. ER05–281–001]

Take notice that on January 21, 2005, Duke Energy Corporation, on behalf of Duke Electric Transmission (collectively Duke) filed an amendment of its December 1, 2004 filing of an executed revised Network Integration Service Agreement with North Carolina Electric Membership Corporation (NCEMC) which is designated as Fourth Revised Service Agreement No. 208 under Duke Electric Transmission FERC Electric Tariff Third Revised Volume No. 4.

Duke states that copies of the filing were served on NCEMC and the South Carolina and North Carolina State public service commissions.

Comment Date: 5 p.m. eastern time on February 11, 2005.

15. JPMorgan Chase Bank, N.A.

[Docket No. ER05–283–002]

Take notice that on January 24, 2005, JPMorgan Chase Bank, N.A. (JPMCB) submitted an amendment to its filing dated January 13, 2005 on market power analysis to reflect recent changes in generation ownership in Docket No. ER05–283–002. JPMCB states that this filing replaces the market power analysis filed on January 13, 2005, in support of: JPMCB's December 2, 2004 request for acceptance of JPMCB rate schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission regulations. JPMCB also states that it intends to engage in wholesale electric energy and capacity transactions as a marketer and a broker. JPMCB indicates that it is not in the business of generating or transmitting electric power.

Comment Date: 5 p.m. eastern time on February 14, 2005.

16. PacifiCorp

[Docket No. ER05–296–001]

Take notice that on January 24, 2005, PacifiCorp tendered for filing in accordance with 18 CFR 35 of the Commission's rules and regulations an amendment to its filing dated December 3, 2004 under FERC Docket No. ER05–296–000.

PacifiCorp states that copies of this filing were supplied to the Public Utility Commission of Oregon, the Washington Utilities and Transportation Commission, and the Milton-Freewater Electric Department.

Comment Date: 5 p.m. eastern time on February 14, 2005.

17. PacifiCorp

[Docket No. ER05–299–001]

Take notice that on January 24, 2005 PacifiCorp tendered for filing in accordance with 18 CFR 35 of the Commission's rules and regulations an amendment to its filing dated December 3, 2004 under FERC Docket No. ER05–299–000.

PacifiCorp states that copies of this filing were supplied to the Public Utility Commission of Oregon, the Washington Utilities and Transportation Commission, and the Central Lincoln People's Utility District.

Comment Date: 5 p.m. eastern time on February 14, 2005.

18. PacifiCorp

[Docket No. ER05–301–001]

Take notice that on January 24, 2005, PacifiCorp tendered for filing in accordance with 18 CFR 35 of the Commission's rules and regulations an amendment to its filing dated December 3, 2004 under FERC Docket No. ER05–301–000.

PacifiCorp states that copies of this filing were supplied to the Public Utility Commission of Oregon, the Washington Utilities and Transportation Commission, and the Utah Associated Municipal Power Systems.

Comment Date: 5 p.m. eastern time on February 14, 2005.

19. Telemagine, Inc.

[Docket Nos. ER05–419–001, ER05–419–002]

Take notice that on January 21, 2005 and January 27, 2005, Telemagine, Inc. (Telemagine) filed amendments to its January 4, 2005 petition for acceptance of initial rate schedule, waivers and blanket authority.

Comment Date: 5 p.m. eastern time on February 14, 2005.

20. Transmission Owners of the Midwest Independent, Transmission System Operator Inc.

[Docket No. ER05–447–001]

Take notice that on January 26, 2005, the Transmission Owners of the Midwest Independent Transmission System Operator (Midwest ISO Transmission Owners) submitted an amendment to the proposed Schedule 23 to the Midwest Independent Transmission System Operator, Inc.'s tariff, that was filed January 13, 2005 in Docket No. ER05–447–000.

The Midwest ISO Transmission Owners state that they are serving this filing on all Midwest ISO's affected customers as well as on all applicable State commissions. The Midwest ISO also states that it will post a copy on its home page.

Comment Date: 5 p.m. eastern time on February 4, 2005.

21. Public Service Company of New Mexico

[Docket No. ER05–471–000]

Take notice that on January 21, 2005, Public Service Company of New Mexico (PNM) submitted for filing two executed service agreements with Texas-New Mexico Power Company (TNMP) for firm point-to-point transmission service. PNM requests a January 1, 2005 effective date for each agreement.

PNM states that copies of the filing have been sent to TNMP, the New Mexico Public Regulation Commission and the New Mexico Attorney General.

Comment Date: 5 p.m. eastern time on February 11, 2005.

22. California Independent System Operator Corporation

[Docket No. ER05–479–000]

Take notice that on January 21, 2005, the California Independent System Operator Corporation (ISO) submitted an informational filing in accordance with Article IX, section B of the Stipulation and Agreement approved by the Commission on May 28, 1999, California Independent System Operator Corp., 87 FERC ¶ 61,250 (1999) (Stipulation and Agreement). ISO states that this provision requires the ISO to provide on a confidential basis to the Commission: (1) Information regarding any notice from an RMR Unit requesting a change of Condition; (2) the date the chosen Condition will begin; and (3) if the change is from Condition 2, the applicable level of Fixed Option Payment. ISO further states as required by the provision, it has provided notice of the changes of condition described in the informational filing (subject to the applicable Non-Disclosure and Confidentiality Agreement in the RMR Contract) to the designated RMR contact persons at the California Public Utilities Commission, the California Electricity Oversight Board, the applicable Responsible Utilities, and the relevant RMR Owners.

Comment Date: 5 p.m. eastern time on February 11, 2005.

23. Pacific Gas and Electric Company

[Docket No. ER05–480–000]

Take notice that on January 21, 2005, Pacific Gas and Electric Company (PG&E), submitted proposed amendments to the Scheduling Coordinator Services Tariff, FERC Electric Tariff First Revised Volume No.

9 to recover the cost PG&E incurs from the California Independent System Operator Corporation as Scheduling Coordinator for certain existing transmission service customers.

PG&E states that copies of this filing have been served upon the California Public Utilities Commission and all parties designated on the official service lists in Docket Nos. ER00–565–000 and ER04–1233–000.

Comment Date: 5 p.m. eastern time on February 11, 2005.

24. Trimont Wind I LLC

[Docket No. ER05–481–000]

Take notice that on January 21, 2005, Trimont Wind I LLC (Trimont) submitted an application for authorization to sell energy, capacity and ancillary services at market-based rates. Trimont also requests that the Commission grant waivers and blanket approvals provided to applicants that receive authority for market-based rates.

Comment Date: 5 p.m. eastern time on February 11, 2005.

25. Cottonwood Energy Company LP

[Docket No. ER05–483–000]

Take notice that on January 24, 2005, Cottonwood Energy Company LP, (Cottonwood) submitted for filing, pursuant to section 205 of the Federal Power Act (16 U.S.C. 824d), and part 35 of the Commission's regulations (18 CFR part 35), a rate schedule for reactive power to be provided under the amended and restated interconnection agreement between Cottonwood Energy Company LP and Entergy Gulf States, Inc. Cottonwood requests an effective date of February 1, 2005.

Comment Date: 5 p.m. eastern time on February 14, 2005.

26. Puget Sound Energy, Inc.

[Docket No. ER05–484–000]

Take notice that on January 24, 2005, Puget Sound Energy, Inc. (Puget Sound Energy) filed with the Commission an agreement for a temporary puget sound area and Northern Intertie Redispatch Pilot Program, which establishes a temporary, voluntary redispatch program on the Federal Columbia River Transmission System, which is owned and operated by the Bonneville Power Administration. Puget Sound Energy requests an effective date of December 8, 2004.

Comment Date: 5 p.m. eastern time on February 14, 2005.

27. West Texas Wind Energy Partners, L.P.

[Docket No. ER05–486–000]

Take notice that on January 24, 2005, West Texas Wind Energy Partners, L.P. (West Texas Wind) tendered for filing a notice of cancellation pursuant to 18 CFR 35.15 to reflect the cancellation of its market-based rate tariff, designated as FERC Electric Tariff, Original Volume No. 1, that was originally accepted for filing in Docket No. ER98–1965–000.

West Texas Wind states that copies of the filing were served upon the Florida Public Service Commission.

Comment Date: 5 p.m. eastern time on February 14, 2005.

28. FPL Energy Cowboy Wind, LLC

[Docket No. ER05–487–000]

Take notice that on January 24, 2005, FPL Energy Cowboy Wind, LLC (FPLE Cowboy Wind) submitted an application for market-based rate authority.

FPLE Cowboy Wind states that copies of the filing were served upon the Florida Public Service Commission.

Comment Date: 5 p.m. eastern time on February 14, 2005.

29. Deseret Generation & Transmission Co-operative, Inc.

[Docket No. ER05–491–000]

Take notice that on January 24, 2004, Deseret Generation & Transmission Co-operative, Inc. (Deseret) submitted a filing detailing a wholesale power cost rebate for 2004 to each of its six member cooperatives under Service Agreement Nos. 1 through 6 of FERC Electric Tariff, Original Volume No. 1. Deseret requests an effective date of January 24, 2005.

Deseret states that a copy of this filing has been provided to each of Deseret's members.

Comment Date: 5 p.m. eastern time on February 14, 2005.

Standard Paragraph

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 comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to 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.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–418 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP04–366–000]

Gulf South Pipeline Company, LP; Notice of Availability of the Environmental Assessment for the Proposed Jackson Gas Storage Expansion Project

January 31, 2005.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) on the natural gas pipeline facilities proposed by Gulf South Pipeline Company, LP (Gulf South) in the above-referenced docket number.

The EA was prepared to satisfy the requirements of the National Environmental Policy Act. The staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The EA assesses the potential environmental effects of the construction and operation of the proposed Jackson Gas Storage Expansion Project. Gulf South wants to expand the capacity of its facilities in Rankin County, Mississippi.

In Docket No. CP04–366–000, Gulf South proposes to construct, operate, and maintain the following facilities at the existing Jackson Gas Storage Facility.

- Up to three (3) storage injection/withdrawal wells, 8-inch well head lines, well head measurement, one (1) pig launcher, and other appurtenant

auxiliary facilities on a proposed well pad site that is owned by Gulf South.

• Approximately 2.37 miles of 16-inch storage pipeline to facilitate injection and withdrawal to and from the new wells. The new 16-inch pipeline will connect with the 8-inch well head lines and will tie in to Gulf South's existing 16-inch storage pipeline.

• One (1) pig receiver and other appurtenant auxiliary facilities at the interconnect site for the proposed and existing 16-inch storage pipelines.

In connection with the drilling of the new storage wells, the total overall storage capacity of the Jackson Storage Field would be increased by approximately 2.4 billion cubic feet (Bcf).

The EA has been placed in the public files of the FERC. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Copies of the EA have been mailed to Federal, state and local agencies, public interest groups, interested individuals, newspapers, and parties to this proceeding.

Any person wishing to comment on the EA may do so. To ensure consideration prior to a Commission decision on the proposal, it is important that we receive your comments before the date specified below. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

• Send an original and two copies of your comments to: Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426;

• Label one copy of the comments for the attention of the Gas Branch 2, PJ11.2.

• Reference Docket No. CP04–366–000; and

• Mail your comments so that they will be received in Washington, DC on or before March 2, 2005.

Please note that we are continuing to experience delays in mail deliveries from the U.S. Postal Service. As a result, we will include all comments that we receive within a reasonable time frame in our environmental analysis of this project. However, the Commission strongly encourages electronic filing of any comments or interventions or protests to this proceeding. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide. Before you can file comments you will need to create a free account which can be created by clicking on ''Sign-up.''

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. Go to *http://www.ferc.gov/esubscribenow.htm.*

Magalie R. Salas,

Secretary.

[FR Doc. E5–451 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

[1] Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF05–3–000]

Jewell Ridge Pipeline Company LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed Jewell Ridge Pipeline Project and Request for Comments on Environmental Issues

January 31, 2005.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Jewell Ridge Pipeline Project involving construction and operation of facilities by the Jewell Ridge Pipeline Company, LLC (JRP) in (Tazwell, Smyth, and Russell counties, VA).[1] These facilities would consist of approximately 30 miles of 20 inch diameter pipeline and modification to the existing compressor station facility. This EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The pipeline company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' was attached to the project notice JRP provided to landowners. This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is available for viewing on the FERC Internet Web site (http://www.ferc.gov).

Summary of the Proposed Project

JRP wants to expand the capacity of its facilities in Virginia to transport an

[1] JRP is beginning NEPA pre-filing of an application with the Commission under section 7 of the Natural Gas Act and Part 157 of the Commission's regulations.

additional 100,000 dekatherms per day of natural gas to the existing East Tennessee Gas Pipeline System. JRP seeks authority to construct and operate:

Facilities (2005/2006)

- Approximately 30 miles of 20-inch-diameter pipeline and associated facilities; and to
- Modify the existing Jewell Ridge Compressor Station in Tazewell County, Virginia; The general location of the project facilities and alternative routes under consideration are shown in Appendix 1.[2]

Land Requirements for Construction

Construction of the proposed facilities would require about 363 acres of land. Following construction, about 120 acres would be maintained as permanent Right-Of-Way. The remaining 243 acres of land would be restored and allowed to revert to its former use.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission staff requests public comments on the scope of the issues to address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their constituents of this proposed action and encourage them to comment on their areas of concern.

In the EA we [3] will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils.
- Land use.
- Water resources, fisheries, and wetlands.
- Cultural resources.
- Vegetation and wildlife.
- Air quality and noise.
- Endangered and threatened species.
- Public safety.

We will also evaluate possible alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

To ensure your comments are considered, please carefully follow the instructions in the public participation section beginning on page 4.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by JRP. This preliminary list of issues may be changed based on your comments and our analysis.

- Several federally/State listed endangered or threatened species may occur in the project area.
- An un-quantified amount of prime farmland soils would be impacted during construction activity.
- Three alternative routes are under consideration, although JRP has identified Alternative Route 3 as the likely preferred alternative (*see* Appendix 1).

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, alternatives to the proposal (including alternative routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.
- Label one copy of the comments for the attention of Gas Branch 3, DG2E.
- Reference Docket No. PF05–3–000.
- Mail your comments so that they will be received in Washington, DC on or before March 4, 2005.

Please note that we are continuing to experience delays in mail deliveries from the U.S. Postal Service. As a result, we will include all comments that we receive within a reasonable time frame in our environmental analysis of this project. However, the Commission strongly encourages electronic filing of any comments or interventions or protests to this proceeding. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide. Before you can file comments you will need to create a free account, which can be created by clicking on ''Login to File'' and then ''New User Account.'' You will be asked to select the type of filing you are making. This filing is considered a ''Comment on Filing.''

Public Scoping Meeting and Site Visit

In addition to or in lieu of sending written comments, we invite you to attend the public scoping meeting we will conduct in the project area. The location and time for the meeting is listed below:

February 22, 2005; 7 p.m. (e.s.t.),
Chilhowie High School,
1160 East Lee Highway,
P.O. Box 2280,
Chilhowie, Virginia 24319.
Phone: (276) 646–8966.
Fax: (276) 646–5951.
Principal—Steve Reedy.

February 23, 2005; 7 p.m. (e.s.t.),
Southwest Virginia Community College,
369 College Road, Route 19,
Richlands, Virginia 24641.
Contact: Pauline Taylor.
(276) 964–7619.

The public scoping meeting is designed to provide state and local agencies, interested groups, affected landowners, and the general public with more detailed information and another opportunity to offer your comments on the proposed project. Interested groups and individuals are encouraged to attend the meeting and to present comments on the environmental issues

[2] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of all appendices, other than Appendix 1 (maps), are available on the Commission's Web site at the ''eLibrary'' link, and all appendices, including Appendix 1are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

[3] ''We'', ''us'', and ''our'' refer to the environmental staff of the Office of Energy Projects (OEP).

they believe should be addressed in the EA. A transcript of the meeting will be made so that your comments will be accurately recorded.

If you do not want to send comments at this time but still want to remain on our mailing list, please return the Information Request (Appendix 4). If you do not return the Information Request, you will be taken off the mailing list.

We may mail the EA for comment. If you are interested in receiving it, please return the Information Request (Appendix 4). If you do not return the Information Request, you will be taken off the mailing list.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding known as an ''intervenor''. Intervenors play a more formal role in the process. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must send one electronic copy (using the Commission's eFiling system) or 14 paper copies of its filings to the Secretary of the Commission and must send a copy of its filings to all other parties on the Commission's service list for this proceeding. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) (*see* Appendix 2).[4] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your environmental comments considered.

Environmental Mailing List

An effort is being made to send this notice to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project. This includes all landowners who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within distances defined in the Commission's regulations of certain aboveground facilities. By this notice we are also asking governmental agencies, especially those in Appendix 3, to express their interest in becoming cooperating agencies for the preparation of the EA.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. Go to *http://www.ferc.gov/esubscribenow.htm.*

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or (202) 208–1659 (TTY), or send a FAX to (202) 208–2106 with the required accommodations.

Finally, public meetings or site visits will be posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Magalie R. Salas,

Secretary.

[FR Doc. E5–449 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

[4] Interventions may also be filed electronically via the Internet in lieu of paper. *See* the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP03–80–001]

Eastern Shore Natural Gas Company; Notice of Intent To Prepare an Environmental Assessment for the Proposed Eastern Shore Natural Gas Company's Amended 2003–2005 Expansion Project and Request for Comments on Environmental Issues

January 31, 2005.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of Eastern Shore Natural Gas Company's (ESNG) proposal to amend its certificate for its 2003–2005 Expansion Project. ESNG proposes to construct additional facilities to increase its system's capacity by 7,450 Dekatherms per day. The facilities would consist of four new pipeline segments on ESNG's existing system in Chester County, Pennsylvania and New Castle, Kent, and Sussex Counties, Delaware.

This notice announces the opening of the scoping period that will be used to gather environmental input from the public and interested agencies on the project. Please note that the scoping period will close on March 2, 2005.

This notice is being sent to potentially affected landowners; Federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American Tribes, other interested parties; local libraries and newspapers. State and local government representatives are asked to notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The pipeline company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*http://*

www.ferc.gov). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is available for viewing on the FERC Internet Web site (*http://www.ferc.gov*).

Background

In the Commission's October 8, 2003 certificate order, ESNG was authorized to construct and operate certain mainline looping, upgrade a measuring and regulating station, and construct and operate a new pressure control station in three phases over a period of three years, 2003 through 2005.

Phase I consisted of the upgrade of the Parkesburg Measuring and Regulating Station in Chester County, Pennsylvania. Phase II consisted of construction of approximately 2.7 miles of 16-inch-diameter pipeline in Chester County, Pennsylvania. Phase III, as currently certificated, consists of approximately 3.0 miles of 16-inch-diameter pipeline. Construction of both Phase I and II has been completed and they are in service. Phase III would be constructed in 2005.

ESNG filed its original application in April 2003. At that time ESNG did not foresee additional customer growth which could result in a forecasted deficiency of firm capacity. Therefore, by requesting an amendment to it's certificate, ESNG will be able to provide for it's customer's increased volume requirements.

After experiencing a relatively cold January 2004 and continued growth of their customer base, several of ESNG's customers reviewed their load profiles in anticipation of responding to ESNG's most recent open season for 2006–2008 and realized that their current firm capacity entitlements were deficient under present peak day conditions. ESNG determined that the most practical, efficient, and effective way to seek authorization for the additional capacity requested by its customers for the 2005–2006 heating season was to request an amendment [1] to the certificate issued in Docket No. CP03–80–000.

Summary of the Proposed Project

Segment 1—Chester County, Pennsylvania

• Segment 1 involves the installation of approximately 1.4 miles of 16-inch-diameter loop [2] parallel to ESNG's existing 8-inch-diameter pipeline, located in Highland Township, Chester County, Pennsylvania. The proposed line ties in to the existing 8-inch-diameter pipeline at Glen Run Road and extends in a south-southeasterly direction for 1.4 miles to Lenover Road where it ties in to the existing 16-inch-diameter pipeline completed in 2004 as part of the facilities associated with Phase II of the original certificate under FERC Docket No. CP03–80–000. No aboveground facilities are associated with this segment.

Segment 2—New Castle County, Delaware

• Segment 2 involves the installation of approximately 3.2 miles of 16-inch-diameter loop near Glasgow, Delaware, in New Castle County. The pipeline starts at a point on Pleasant Valley Road approximately 0.5 mile north of Route 40 where it will become an extension of the 16-inch-diameter pipeline approved as part of facilities associated with Phase III of the original certificate. The pipeline route runs southerly along Pleasant Valley Road for approximately 0.5 mile. The pipeline route then runs easterly along the north side of Route 40 for approximately 0.9 mile to an existing pipeline right-of-way. The route then diverts off of Route 40 and runs southerly along an existing ESNG pipeline right-of-way for approximately 0.3 mile. The route then runs easterly for approximately 0.5 mile until it intersects with Business Highway 896. The route then runs southerly along Business Highway 896 for approximately 0.9 mile until the intersection with Porter Road. The proposed pipeline then continues easterly along Porter Road for approximately 0.1 mile. This segment will include a new pressure control/regulator station to be constructed at MP 3.1.

Segment 3—Sussex County, Delaware

• Segment 3 involves the installation of approximately 10.3 miles of 6-inch-diameter loop from the City of Milford to the Town of Milton, in Sussex County, Delaware. This segment extends from ESNG's existing 6-inch-diameter pipeline on the east side of the City of Milford along Route 14 and Business Route 1 for approximately 2.0 miles, generally running in a southerly direction to Route 30. The route then continues southerly for approximately 8.0 miles along Route 30 to an intersection with Route 16 west of the City of Milton. This segment has a proposed new meter and regulation station constructed at the southern terminus.

Segment 4—Sussex County, Delaware

• Segment 4 involves the installation of approximately 6.0 miles of 10-inch-diameter loop parallel to ESNG's existing 6-inch-diameter pipeline between the Towns of Laurel and Delmar in Sussex County, Delaware. The proposed route ties in to ESNG's existing 6-inch-diameter pipeline south of the Town of Laurel. The route then runs southerly along Route 13 for roughly 6.0 miles to the Town of Delmar, Delaware north of the Delaware-Maryland State line. The proposed 10-inch-diameter pipeline ties in to ESNG's existing 6-inch-diameter pipeline on the southern terminus as well. No aboveground facilities are associated with this segment.

The location of the project facilities is shown in Appendix 1.[3]

Land Requirements for Construction

Construction of the proposed facilities would require about 220.5 acres of land. Following construction, about 8.9 acres would be maintained as new above ground facility sites and right-of-way. The remaining 211.6 acres of land would be restored and allowed to revert to its former use.

The EA Process

We [4] are preparing this EA to comply with the National Environmental Policy Act (NEPA) which requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission staff requests public comments on the scope of the issues to address in the EA. All comments received are considered during the

[1] ESNG's application was filed with the Commission under section 7 of the Natural Gas Act and part 157 of the Commission's regulations.

[2] A loop is a segment of pipeline installed adjacent to an existing pipeline and which connects to the existing pipeline at both ends of the loop. The loop allows more gas to be moved through the system.

[3] The appendices referenced in this notice are not being printed in the **Federal Register.** Copies of all appendices, other than appendix 1 (maps), are available on the Commission's Web site at the ''eLibrary'' link or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

[4] ''We'', ''us'', and ''our'' refer to the environmental staff of the Office of Energy Projects (OEP).

preparation of the EA. By this notice, we are also asking Federal, state, and local agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. Agencies that would like to request cooperating status should follow the instructions for filing comments below.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

Currently Identified Environmental Issues

In the EA, we will discuss impacts that could occur as a result of the construction and operation of the project. We will also evaluate possible alternatives to the proposed project or portions of the project.

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by ESNG. This preliminary list of issues may be changed based on your comments and our analysis.

Project-related impact on:

- 98 residences/structures within 50 feet of the construction workspace.
- 1.1 acres of wetland.
- 53.8 acres of agricultural land.
- Six federally-listed threatened and endangered species potentially in the project area.
- 28 road crossings.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, alternatives to the proposal (including alternative locations and routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.
- Label one copy of the comments for the attention of Gas Branch 1.
- Reference Docket Number CP03–80–001.
- Mail your comments so that they will be received in Washington, DC on or before March 2, 2005.

Please note that the Commission strongly encourages electronic filing of any comments or interventions or protests to this proceeding. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide. Before you can file comments, you will need to create an account which can be created on-line.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding known as an ''intervenor''. Intervenors play a more formal role in the process. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must send one electronic copy (using the Commission's eFiling system) or 14 paper copies of its filings to the Secretary of the Commission and must send a copy of its filings to all other parties on the Commission's service list for this proceeding. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, see Appendix 2).[5] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your environmental comments considered.

Environmental Mailing List

If you wish to remain on our environmental mailing list, please return the Information Request Form included in Appendix 2. If you do not return this form, you will be removed from our mailing list.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TYY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. Go to *http://www.ferc.gov/esubscribenow.htm.*

Magalie R. Salas,

Secretary.

[FR Doc. E5–450 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

[5] Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–42–000]

Tennessee Gas Pipeline Company; Notice of Intent To Prepare an Environmental Assessment for the Proposed Compressor Station 325 Horsepower Replacement Project and Request for Comments on Environmental Issues

January 26, 2005.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) on Tennessee Gas Pipeline Company's (Tennessee) proposed Compressor Station 325 Horsepower Replacement Project. Tennessee's proposal involves the replacement of the two existing turbines at its Compressor Station 325

in Sussex County, New Jersey with two new turbines.

This notice announces the opening of the scoping period that will be used to gather environmental input from the public and interested agencies on the project. Please note that the scoping period will close on February 25, 2005.

This notice is being sent to potentially affected landowners; Federal, State, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. This includes all owners of property within 0.5-mile of Tennessee's Compressor Station 325. State and local government representatives are asked to notify their constituents of this planned project and encourage them to comment on their areas of concern.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility on My Land? What Do I Need To Know?'' is available for viewing on the FERC Internet Web site (*http://www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including how to participate in the Commission's proceedings.

Summary of the Proposed Project

Tennessee seeks the authority to replace the two turbines at its existing Compressor Station 325 in order to comply with Reasonably Available Control Technology standards set by the United States Environmental Protection Agency and the New Jersey Department of Environmental Protection regarding nitrogen oxide emissions.

The existing turbines are both site-rated at 3,500 horsepower; the replacements would be site-rated at 4,721 horsepower. Therefore, the proposed action would increase the total authorized compressor station output by 2,442 horsepower and increase pipeline flow capacity by 18,000 dekatherms per day in the vicinity of compressor station. Construction of the proposed project would commence on or about April 2006 and Tennessee would place the project in-service in November 2006. The general location of the project is shown in Appendix 1.[1]

[1] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of all appendices, other than Appendix 1 (maps), are available on the Commission's Web site at the ''eLibrary'' link or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

Land Requirements for Construction

Compressor Station 325 is located on a 93.59-acre lot. However, the fenced station yard is 4.92 acres in size and is served by a paved access road. The private access road would not be improved, and no temporary access roads would be constructed. All construction activities would take place within the previously disturbed, graveled areas inside the fenced station yard. No expansion of the fenced station yard is proposed.

The EA Process

We[2] are preparing this EA to comply with the National Environmental Policy Act (NEPA) which requires the Commission to take into account the environmental impact that could result if it authorizes Tennessee's proposed project. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, we are requesting public comment on the scope of the issues to address in the EA. All comments received will be considered during the preparation of the EA. By this notice, we are also asking Federal, State, and local agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. Agencies that would like to request cooperating status should follow the instructions for filing comments provided below.

The EA will present our independent analysis of the issues. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, State, and local agencies, public interest groups, interested individuals, potentially affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

To ensure your comments are considered, please carefully follow the instructions in the public participation section below.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, alternatives to the proposal, and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.
- Label one copy of the comments for the attention of Gas Branch 1.
- Reference Docket No. CP05–42–000.
- Mail your comments so that they will be received in Washington, DC on or before February 25, 2005.

The Commission strongly encourages electronic filing of any comments or interventions or protests to this proceeding. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide. Before you can file comments you will need to create a free account which can be created on-line.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding known as an ''intervenor''. Intervenors play a more formal role in the process. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must send one electronic copy (using the Commission's eFiling system) or 14 paper copies of its filings to the Secretary of the Commission and must send a copy of its filings to all other parties on the Commission's service list for this proceeding. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) (*see* Appendix 2).[3] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Office of Energy Projects.

[3] Interventions may also be filed electronically via the Internet in lieu of paper. *See* the previous discussion on filing comments electronically.

cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your environmental comments considered.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. To register for this service, go to *http://www.ferc.gov/esubscribenow.htm.*

Magalie R. Salas,

Secretary.

[FR Doc. E5–428 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Draft License Application and Preliminary Draft Environmental Assessment and Request for Preliminary Terms and Conditions

January 27, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* New major license.

b. *Project No.:* 2219–013.

c. *Applicant:* Garkane Energy Cooperative, Inc. (Garkane).

d. *Name of Project:* Boulder Creek Hydroelectic Project.

e. *Location:* On Boulder Creek about 6 miles north of the town of Boulder in Garfield County, Utah. About 31.74 acres are located on the Dixie National Forest.

f. *Applicant Contact:* John Spendlove, P.E., Jones and DeMille Engineering, 1535 South 100 West, Richfield, UT 84710; (435) 896–8266.

g. *FERC Contact:* Dianne Rodman (202) 502–6077, e-mail: *Dianne.rodman@ferc.gov*.

h. Garkane mailed a copy of the Preliminary Draft Environmental Assessment (PDEA) and draft application to interested parties on January 13, 2005. The PDEA and draft application were filed on January 18, 2005.

i. With this notice we are soliciting preliminary terms, conditions, and recommendations on the PDEA and draft license application. All comments on the PDEA and draft license application should be sent to the address above in item (f) with one copy filed with the Commission at the following address: Federal Energy Regulatory Commission, Magalie R. Salas, Secretary, 888 First St., NE., Washington, DC 20426. All comments must include the project name and number, and bear the heading ''Preliminary Comments,'' Preliminary Recommendations,'' ''Preliminary Terms and Conditions,'' or ''Preliminary Prescriptions.'' Any party interested in commenting must do so before April 1, 2005.

j. Comments and preliminary recommendations, terms and conditions, and prescriptions may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

k. With this notice, we are initiating consultation with the State Historic Preservation Officer (SHPO), as required by section 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

l. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

The PDEA and draft application are also available upon the Web site *http://www.jonesanddemille.com.*

Magalie R. Salas,

Secretary.

[FR Doc. E5–422 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–2330–029 and ER04–1255–000]

New England Power Pool and ISO New England Inc.; Notice of Technical Conference

January 28, 2005.

On January 13, 2005 ISO New England, Inc. requested that the Federal Energy Regulatory Commission convene a technical conference on Friday, March 4, 2005, in Boston, Massachusetts, to address the prioritization and coordination of the interrelated market improvements currently being developed and considered by the ISO and market participants in New England. Specifically, the ISO requests that the Commission facilitate discussions regarding the day-ahead load response program (DALRP) and the special case nodal pricing (SCNP), including a discussion of how those programs fit within the overall market development plan for New England.

To this end, the Commission will host a technical conference on Friday, March 4, 2005, to address the issues raised by the above described request. The conference will be held at the Seaport World Trade Center (Harborview Ballroom), 200 Seaport Boulevard, Boston, Massachusetts 02210. The conference is scheduled to begin at 9 a.m. and end at approximately 4 p.m. (e.s.t.). Commissioners are expected to attend and participate. An agenda will be forthcoming.

Although registration is not a strict requirement, in-person attendees are asked to register for the conference on-line by close of business on Wednesday, March 2, 2005 at *http://www.ferc.gov/whats-new/registration/iso-03-04-form.asp.*

Transcripts of the conference will be immediately available from Ace Reporting Company (202–347–3700 or 1–800–336–6646) for a fee. They will be available for the public on the Commission's eLibrary system seven calendar days after FERC receives the transcript. Additionally, Capitol Connection offers the opportunity for

remote listening of the conference via Real Audio or a Phone Bridge Connection for a fee. Persons interested in making arrangements should contact David Reininger or Julia Morelli at the Capitol Connection (703–993–3100) as soon as possible or visit the Capitol Connection Web site at *http://www.capitolconnection.org* and click on ''FERC.''

For more information about the conference, please contact Anna Cochrane at (202) 502–6357, *anna.cochrane@ferc.gov* or Sarah McKinley at (202) 502–8004, *sarah.mckinley@ferc.gov.*

Magalie R. Salas,

Secretary.

[FR Doc. E5–441 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD05–1–000]

Principles for Efficient and Reliable Reactive Power Supply and Consumption; Notice of Technical Conference

January 31, 2005.

Take notice that a technical conference will be held on March 8, 2005, from approximately 9 a.m. until 5 p.m. (EST) in the Commission Meeting Room on the second floor of the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC. All interested persons may attend, and registration is not required. Commissioners are expected to participate.

The technical conference will address specific issues raised in the staff report regarding reactive power supply for the nation's bulk power that will be issued on February 4, 2005. The goal of the technical conference is to discuss the proper regulatory policy toward reactive power supply and consumption.

The Commission is now soliciting nominations for speakers at the technical conference. Persons wishing to nominate themselves as speakers should do so using this electronic link: *http://www.ferc.gov/whats-new/registration/rp-03-08-speaker-form.asp.* Such nominations must be made before the close of business, Friday, February 18, 2005, so that an agenda for the technical conference can be drafted and published.

Transcripts of the conference will be immediately available from Ace Reporting Company (202–347–3700 or 1–800–336–6646) for a fee. They will be available for the public on the Commission's eLibrary system seven calendar days after FERC receives the transcript. Additionally, Capitol Connection offers the opportunity for remote listening and viewing of the conference. It is available for a fee, live over the Internet, by phone or via satellite. Persons interested in receiving the broadcast, or who need information on making arrangements should contact David Reininger or Julia Morelli at the Capitol Connection (703–993–3100) as soon as possible or visit the Capitol Connection Web site at *http://www.capitolconnection.gmu.edu* and click on ''FERC.''

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or (202) 208-1659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

For more information about the conference, please contact Derek Bandera at (202) 502–8031 (*Derek.bandera@ferc.gov*) or Sarah McKinley at (202) 502–8004 (*sarah.mckinley@ferc.gov*).

Magalie R. Salas,

Secretary.

[FR Doc. E5–452 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the Record Communications; Public Notice

January 28, 2005.

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or prohibited off-the-record communication relevant to the merit's of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of exempt communications recently received in the Office of the Secretary. The communications listed are grouped by docket numbers. These filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary (FERRIS) link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC, Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket no.	Date filed	Presenter or requester
Exempt:		
1. CP04–36–000	1–26–05	Hon. Patrick C. Lynch
2. CP04–36–000,	1–27–05	Hon. Ranch Kimball
3. CP04–37–000	1–24–05	Hon. Victor G. Carrillo, Hon. Michael Williams, Hon. Charles R. Matthews.

Docket no.	Date filed	Presenter or requester
4. CP04–37–000	1–24–05	Hon. John Cornyn.
5. CP04–293–000, CP04–223–000, CP04–36–000, CP04–41–000.	1–18–05	Hon. Jack Reed.
6. CP04–293–000, CP04–223–000, CP04–36–000, CP04–41–000.	1–24–05	Hon. Lincoln Chafee.
7. CP04–386–000, CP04–400–000	1–18–05 (1–13–05 Memo to file)	Jennifer Kerrigan.
8. CP04–386–000,CP04–400–000	1–26–05 (1–24–05 Memo to file)	Jennifer Kerrigan.
9. CP05–3–000	1–18–05 (Memo to file re: 1–12–05 Mtg.)	Monica DeAngelo.
10. CP05–3–000	1–18–05 (Memo to file re: 1–13–05 Mtg.)	Monica DeAngelo.
11. CP05–19–000	1–18–05	Jennifer Kerrigan.
12. Project No. 1971–079	1–24–05	Steven A. Ellis.
13. Project No. 2150–033	1–18–05	Kenneth L. Brettmann
14. Project No. 2237–013	1–12–05	Nicholas Jayjack/Jim Long, *et al.*[1]

[1] Memo to File from Nicholas Jayjack attaching email communications and documents provided to the Study Dispute Resolution Panel for the Morgan Falls Hydroelectric Project proceeding.

Magalie R. Salas,

Secretary.

[FR Doc. E5–445 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM05–2–000]

Policy for Selective Discounting by Natural Gas Pipelines; Errata Notice

January 26, 2005.

On January 25, 2005, the Commission issued a Notice of Extension of Time in the above-docketed proceeding. The date for filing comments should be changed from ''May 2, 2005'' to ''March 2, 2005''. Comments on the NOI are due March 2, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–423 Filed 2–3–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7869–4]

Clean Air Act Operating Permit Program; Petition for Objection to State Operating Permits; Dow Chemical Company

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition to object to State operating permits.

SUMMARY: The EPA Administrator signed an order, dated December 22, 2004, denying the petition to object to State operating permits issued by the Louisiana Department of Environmental Quality (LDEQ) for the Light Hydrocarbon III and Cellulose plants at the Dow Chemical Company's facilities in Plaquemine, Iberville Parish, Louisiana. Pursuant to section 505(b)(2) of the Clean Air Act (Act), the petitioner may seek judicial review of this petition response in the United States Court of Appeals for the Fifth Circuit. Any petition must be filed within 60 days of the date this notice appears in the **Federal Register**, pursuant to section 307(d) of the Act.

ADDRESSES: You may review copies of the final order, the petition, and other supporting information at EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733. If you wish to examine these documents, you should make an appointment at least 24 hours before visiting day. The final order is also available electronically at the following address: *http://www.epa.gov/region07/programs/artd/air/title5/petitiondb/petitiondb2002.htm*.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Stanton, Air Permits Section, Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–8377, or e-mail at *Stanton.Marya@epa.gov*.

SUPPLEMENTARY INFORMATION: The Act affords EPA a 45-day period to review, and, as appropriate, object to operating permits proposed by State permitting authorities under Title V of the Act, 42 U.S.C. 7661–7661f. Section 505(b)(2) of the Act authorizes any person to petition the EPA Administrator within 60 days after the expiration of this review period to object to State operating permits if EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the State, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

The Louisiana Environmental Action Network (LEAN) submitted a petition requesting that the Administrator object to title V operating permits issued by LDEQ to the Dow Chemical Company, for modifications to its Light Hydrocarbon III and Cellulose Plants at Dow's facility in Plaquemine, Iberville Parish, Louisiana.

The petition maintains that the permits are inconsistent with the Act because:

(1) The emission reduction credits (ERCs) used as offsets are not valid because the underlying emission reductions were required, and not surplus;

(2) The ERCs are not valid because LDEQ improperly concluded that the underlying emission reductions occurred within 10 years of the date the offsets were used;

(3) Dow's application for ERCs was not timely under the requirements of the Louisiana Administrative Code;

(4) LDEQ's Basis For Decision on the ERC application failed to respond to all reasonable public comments;

(5) The permits should have required controls designed to achieve the Lowest Achievable Emission Rate (LAER) because Dow had insufficient offsets to avoid LAER;

(6) Offsets should have been required for 33.34 tons per year of emission increases of volatile organic compounds from emission points C6 ,C7, and LN, and LDEQ was inconsistent in granting those emission increases while also maintaining that the facilities were in compliance with the previously permitted emissions limitations; and

(7) In establishing the baseline for sulfur dioxide emissions for purposes of determining whether the permits constituted a significant modification, LDEQ failed to either use actual emissions over the preceding two years, or make a determination that a different

time period was more representative of normal source operation.

On December 22, 2004, the Administrator issued an order denying the petition. The order explains the reasons for the Administrator's decision that the petition does not demonstrate that the permits are not in compliance with the Act.

Dated: January 26, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. 05–2181 Filed 2–3–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6660–1]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act, as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in the **Federal Register** dated April 2, 2004 (69 FR 17403).

Draft EISs

ERP No. D–AFS–F65047–IN Rating LO, German Ridge Restoration Project, To Restore Native Hardwood Communities, Implementation, Hoosier National Forest, Tell City Ranger District, Perry County, IN.

Summary: EPA has no objections with the proposed restoration project; however, we recommended that a schedule for prescribed burns and timber removal be included in the FEIS.

ERP No. D–BLM–K65274–NV Rating EC2, Las Vegas Valley Disposal Boundary Project, Disposal and Use of Public Land under the Management of (BLM), Implementation, Clark County, NV.

Summary: EPA expressed environmental concerns about impacts to wetlands and Waters of the U.S., general conformity under the Clean Air Act, the analysis of alternatives, and consultation with tribal governments.

ERP No. D–FHW–C40164–NY Rating EC2, NY Route 17—Elmira to Chemung Project, Proposed Highway Reconstruction, New Highway Construction, Bridge Rehabilitation/ Replacement, Funding and U.S. Army COE Section 404 Permit, Town and City of Elmira, Town of Ashland and Chemung, Chemung County, NY.

Summary: EPA has concerns with the proposed project due to indirect impacts to water quality and wetlands, and suggested firmer mitigation measures be implemented to address these concerns.

ERP No. D–FHW–D40325–PA Rating EC2, U.S. 219 Improvements Project, Meyersdale to Somerset, SR 6219, Section 020, Funding, U.S. COE Section 404 Permits, Somerset County, PA.

Summary: EPA has environmental concerns with the proposed project regarding impacts to wetlands, endangered species, aquatic resources, air quality, and environmental justice.

ERP No. D–FHW–F40426–OH Rating EC2, Eastern Corridor Multi-Modal (Tier 1) Project, To Implement a Multi-Modal Transportation Program between the City of Cincinnati and Eastern Suburbs in Hamilton and Clermont Counties, OH.

Summary: EPA has concerns with the proposed project, primarily regarding a new bridge span across the Little Miami River, a designated Wild and Scenic River. These concerns include unresolved questions regarding visual impacts, and cumulative, indirect and secondary impacts to the river's identified characteristics.

ERP No. D–FHW–J40167–UT Rating EC2, Brown Park Road Project, Reconstruction (Paving) and Partial Re-alignment from Red Creek to Colorado State Line, Diamond Mountain Resource Management Plan Amendment (BLM), U.S. Army COE Section 404 Permit, Daggett County, UT.

Summary: EPA has environmental concerns with the proposed project regarding habitat fragmentation, impacts to wildlife due to vehicle collisions, and the introduction of invasive species.

ERP No. D–NIH–D81035–MD Rating EC2, National Institutes of Health (NIH) Master Plan 2003 Update, National Institutes of Health Main Campus—Bethesda, MD, Montgomery County, MD.

Summary: EPA expressed concerns regarding impacts from land development and storm water management. EPA requested that the final EIS address the function and value of the existing hardwoods that will be lost, and provide an outline of the mitigation.

ERP No. DS–BIA–A65165–00 Rating EC2, Programmatic—Navajo Nation 10-Year Forest Management Plan, New and Updated Information on Alternatives, Chuska Mountains and Defiance Plateau Area, AZ and NM.

Summary: EPA expressed concerns regarding cumulative impacts and implementation of the Range Assessment and Management Plan (RAMP), and requested that existing environmental information be incorporated into the alternatives and cumulative impact analyses.

ERP No. DS–FHW–E40325–NC Rating EC2, Eastern Section of the Winston-Salem Northern Beltway, U.S. 52 south to I–40 Business and I–40 Business south to U.S. 311, Improvements to the Surface Transportation Network, TIP Project Nos. U–2579 and U–2579A, Forsyth County, NC.

Summary: EPA continues to have environmental concerns with the proposed project regarding the number of residential relocations required as well as impacts to aquatic stream habitat and water supply.

Final EISs

ERP No. F–AFS–E65067–00 Land Between the Lakes National Recreation Area, Proposes to Revise TVA's 1994 Natural Resources Management Plan, Development of a Land Management Resource Plan or Area Plan, Gold Pond, Trigg and Lyon Counties, KY and Stewart County, TN.

Summary: The Final EIS has addressed our concerns and EPA has no objections to the project.

ERP No. F–COE–G39041–LA Programmatic EIS—Louisiana Coastal Area (LCA) Ecosystem Restoration Study, Implementation, Tentatively Selected Plan, Mississippi River, LA.

Summary: EPA continues to express full support for the Louisiana Coastal Area Plan, recognizing that the Plan is the appropriate next step in the ongoing effort to address wetland and barrier island loss in coastal Louisiana.

ERP No. F–DHS–D11036–MD National Biodefense Analysis and Countermeasures Center (NBACC) Facility at Fort Detrick, Construction and Operation, Fort Detrick, Frederick County, MD.

Summary: The Final EIS provided adequate responses to EPA's comments.

ERP No. F–FHW–E40795–NC U.S.–17 Interstate Corridor Improvements, south of NC–1127 (Possum Track Road) to north of NC–1418 (Roberson Road) Funding and Permit Issuance, City of Washington and Town of Chocowinity Vicinity, Beaufort and Pitt Counties, NC.

Summary: EPA has no objections to the preferred alternative.

ERP No. F–FHW–F40368–WI U.S.–12 Highway Corridor Project, Improvement from 1H90/94 at Lake Delton south to Ski Hi Road, Selected Preferred Alternative, Funding and U.S. Army COE Section 404 Permit Issuance, Sauk County, WI.

Summary: EPA has no objections to the preferred alternative.

ERP No. F–FHW–F40409–IN IN–25 Transportation Corridor Improvements from I–65 Interchange to U.S. 24, Funding, Right-of-Way and U.S. Army COE Section 404 Permit Issuance, Hoosier Heartland Highway, Tippecanoe, Carroll and Cass Counties, IN.

Summary: EPA has no objections to the preferred alternative.

ERP No. F–FHW–L40206–WA WA–104/Edmonds Crossing Project, Connecting Ferries, Bus and Rail, Funding, NPDES Permit and COE Section 10 and 404 Permits, City of Edmonds, Snohomish County, WA.

Summary: No comment letter was sent to the preparing agency.

Dated: January 25, 2005.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 05–1628 Filed 2–3–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6660–2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/*.

Weekly receipt of Environmental Impact Statements filed January 24, 2005 through January 28, 2005 pursuant to 40 CFR 1506.9.

EIS No. 050029, Final Supplement, FHW, FL, FL–23 Extension (Branan Field-Chaffe Road), Construction from FL–134 (103rd Street) to FL–8 (I–10) and FL–10 (US–90/Beaver Street), NPDES and US Army COE Section 404 Permits Issuance, Clay and Duval Counties, FL, Wait Period Ends: March 7, 2005, Contact: Donald E. Davis (404) 562–9521.

EIS No. 050030, Draft EIS, NPS, CA, Non-Native Deer Management Plan of Axis Deer (Axis axis) and Fallow Deer (Dama dama), Implementation, Point Reyes National Seashore (PRNS) and Golden Gate National Recreation Area, Marin County, CA, Comment Period Ends: April 05, 2005, Contact: Natalie Gates (415) 464–5189.

EIS No. 050031, Final EIS, USA, TX, Fort Bliss, Texas Proposed Leasing of Lands, Proposed Siting, Construction and Operation, by the City of El Paso of a Brackish Water Desalination Plant and Support Facilities, El Paso Water Utilities (EPWU), City of El Pasco, TX and New Mexico, Wait Period Ends: March 7, 2005, Contact: John Barrera (915) 568–3908.

EIS No. 050032, Draft EIS, AFS, WV, Fernow Experimental Forest, To Continue Long-Term Research and Initiate New Research, Involving Removal of Trees, Prescribed Burning, Stem Injection of Selected of Trees, Control Invasive Plant Species, Northeastern Research Station, Parson, Tucker County, WV, Comment Period Ends: March 21, 2005, Contact: Mary Beth Adams (304) 478–2000 Ext 130.

EIS No. 050033, Draft EIS, IBR, NV, Humboldt Project Conveyance, Transferring 83,530 Acres from Federal Ownership to the Pershing County Water Conservation District (PCWCD), Pershing and Lander Counties, NV, Comment Period Ends: April 01, 2005, Contact: Caryn Huntt DeCarlo (775) 884–8352.

EIS No. 050034, Final EIS, NSF, Development and Implementation of Surface Traverse Capabilities in Antarctic Comprehensive Environmental Evaluation, Antarctica, Wait Period Ends: March 7, 2005, Contact: Polly A. Pinhole (703) 292–8033.

EIS No. 050035, Final EIS, AFS, WY, Upper Green River Area Rangeland Project, Propose Site Specific Grazing Management Practices, Bridger-Teton Forest, Sublette, Teton and Fremont Counties, WY, Wait Period Ends: March 7, 2005, Contact: Craig Trulock (307) 367–4326.

EIS No. 050036, Draft EIS, AFS, CA, Burlington Ridge Trails Project, To Eliminate, Reconstruct/or Reroute Unsound Trail Sections, Tahoe National Forest, Yuba River Ranger District, Camptonville, Nevada County, NV, Comment Period Ends: March 21, 2005, Contact: Mary Furney (053) 478–6263.

EIS No. 050037, Draft EIS, AFS, MO, Mark Twain National Forest Land and Resource Management Plan, Implementation, Revise to the 1986 Land and Resource Management Plan, several counties, MO, Comment Period Ends: May 5, 2005, Contact: Laura Watts (573) 341–7471.

EIS No. 050038, Draft EIS, BLM, NM, McGregor Range Resource Management Plan Amendment (RMPA), Implementation, Otero County, NM, Comment Period Ends: May 5, 2005, Contact: Tom Phillips (505) 525–4377.

EIS No. 050039, Draft EIS, AFS, NM, Tajique Watershed Restoration Project, Proposes Fuel Reduction and Restore Forest Health, Cibola National Forest, Torraine County, NM, Comment Period Ends: March 21, 2005, Contact: Vicky Estrada (505) 847–2990.

EIS No. 050040, Final Supplement, AFS, UT, Table Top Exploratory Oil and Gas Wells, New Information from the Approval 1994 Final EIS, Wasatch-Cache National Forest, Evanston Ranger District, Summit County, UT, Wait Period Ends: March 7, 2005, Contact: Roger Kesterson (307) 782–6555.

EIS No. 050041, Final Supplement, BIA, AZ, NM, Programmatic EIS—Navajo Nation 10-Year Forest Management Plan, Selected Preferred Alternative Four, Chuska Mountain and Defiance Plateau Area, AZ and NM, Wait Period Ends: March 7, 2005, Contact: Jonathan Martin (928) 729–7228.

EIS No. 050042, Final EIS, AFS, WY, Tongue Allotment Management Plan, Proposal to Continue Livestock Grazing on All or Portions of the 22 Allotment, Bighorn National Forest, Tongue and Medicine Wheel/Paintrock Ranger Districts, Johnson, Sheridan and Bighorn Counties, WY, Wait Period Ends: March 7, 2005, Contact: Craig L. Yancey (307) 674–2600.

EIS No. 050043, Draft Supplemental EIS, FHW, UT, US 6 Highway Project, Improvements from Interstate 15 (I–15) in Spanish Fork to Interstate (I–70) near Green River, New Information, Funding, Right-of-Way Permit and U.S. Army COE Section 404 Permit, Utah, Wasatch, Carbon, Emery Counties, UT, Comment Period Ends: March 28, 2005, Contact: Jeff Berna (801) 963–0182.

Amended Notices

EIS No. 050000, Draft EIS, AFS, UT, Ogden Ranger District Travel Plan, To Update the Travel Management Plan, Wasatch-Cache National Plan, Ogden Ranger District, Box Elder, Cache, Morgan, Weber and Rich Counties, UT, Comment Period Ends: March 30, 2005, Contact: Rick Vallejos (801) 625–5112. Revision of **Federal Register** Notice Published on 1/28/05: CEQ Comment Period Ending 02/22/2005 has been Extended to 03/01/2005.

EIS No. 250017, Final EIS, NOA, ME, MA, RI, NH, CT, Atlantic Herring Fishery Management Plan, Minimizing Impacts on Essential Fish Habitat of Any Species, Gulf of Maine—Georges Bank, ME, NH, MA, CT and RI, Wait Period Ends: March 1, 2005, Contact: Peter D. Colosi (978) 281–3332. Revision of **Federal Register** Notice Published on 1/28/05: CEQ Comment Period Ending 02/22/

2005 has been Extended to 03/01/2005.

Dated: February 1, 2005.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 05–2177 Filed 2–3–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6660–3]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act, as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in the **Federal Register** dated April 2, 2004 (69 FR 17403).

Draft EISs

ERP No. D–FAA–E51051–FL Rating EC2, Panama City-Bay County International Airport (PFN), Proposed Relocation to a New Site, NPDES Permit and U.S. Army COE Section 404 Permit, Bay County, FL.

Summary: EPA expressed concerns due to wetland and secondary impacts, and requested additional information on secondary development and impacts induced by the proposed airport relocation, wetland mitigation, and the sponsor's site selection process.

ERP No. D–FHW–H40183–00 Rating LO, Council Bluffs Interstate System Improvements Project, Transportation Improve from Missouri River on I–80 to East of the I–480 Interchange, (Tier 1), Pottawattamie County, IA and Douglas County, NB.

Summary: EPA has no objections to the proposed project. ERP No. D–FRC–G03023–TX Rating EC2, Cheniere Corpus Christi Liquefied Natural Gas (LNG) Project, To Provide Facilities for the Importation, Storage and Vaporization of Liquefied Natural Gas, Nueces and San Patricio Counties, TX.

Summary: EPA expressed environmental concerns and requested additional information regarding wetlands mitigation measures, the potential for invasive species introduction, and air quality impacts.

ERP No. D–NIH–G84000–TX Rating LO, Galveston National Laboratory for Biodefense and Emerging Infectious Diseases Research Facility at the University of Texas Medical Branch, Construction, Partial Funding, Grant, Galveston, TX.

Summary: EPA had no objection to the selection of the preferred alternative. However, EPA asked that the Final EIS include a discussion of general air quality conformity.

ERP No. D–STB–G53010–TX Rating EC2, Southwest Gulf Railroad Project, Construction and Operation Exemption, To Transport Limestone from Vulcan Construction Materials (VCM) Quarry to Del Rio Subdivision, Medina County, TX.

Summary: EPA expressed environmental concerns about the proposed project regarding the Spill Prevention, Containment and Countermeasure Plan, aquatic steam crossing mitigation measures, and air quality impacts.

Final EISs

ERP No. F–BIA–L02031–OR Wanapa Energy Center, Construction and Operation a New 1,200 Megawatt (MW) Natural Gas-Fired Electric Power Generating Facility, Confederated Tribes of the Umatilla Indian Reservation (CTUIR), in the City of Hermiston and the Port of Umatilla, OR.

Summary: No formal comment letter was sent.

ERP No. F–FHW–D40093–PA City of Lebanon Bridge Over Norfolk Southern Railroad Tracks Construction Project, 12th Street to Lincoln Avenue, Funding, Lebanon County, PA.

Summary: EPA has no objections to the preferred alternative.

ERP No. F–FHW–F40408–00 Trunk Highway 60 Reconstruction Project, Improvements from 1.8 miles south of the Minnesota-Iowa Border (120th Street) to I–90 north of the City of Worthington, Funding, U.S. Army COE Section 404 and NPDES Permits Issuance, Nobles County, MN and Osceola County, IA.

Summary: EPA has no objections to the preferred alternative.

ERP No. F–FRC–G03022–LA Sabine Pass Liquefied Natural Gas (LNG) and Pipeline Project, Construction and Operation LNG Import Terminal and Natural Gas Pipeline Facilities, Several Permits, Cameron Parish, LA.

Summary: EPA expressed environmental concerns and requested additional information regarding post-construction monitoring of wetland mitigation and sediment toxicity testing of dredged material. EPA will also continue coordination efforts with the U.S. Army Corps of Engineers as the Aquatic Resources Mitigation Plan is finalized and the Clean Water Act Section 404 permit application is reviewed.

ERP No. F–FTA–D54041–VA Dulles Corridor Rapid Transit Project, High-Quality and High-Capacity Transit Service in the Dulles Corridor, West Falls Church Metrorail Station in Fairfax County to the Vicinity of Route 772 in Loudoun County, VA.

Summary: EPA's comments have been adequately addressed in the Final EIS and has no objections to the preferred alternative.

ERP No. F–IBR–K39088–CA Sacramento River Settlement Contractors (SRSC), To Renew the Settlement Contractors Long-Term Contract Renewal for 145 Contractors, Central Valley Project (CVP), Sacramento River, Shasta, Tehama, Butte, Glenn, Colusa, Sutter, Yolo, Sacramento, Portion of Placer and Solano Counties, CA.

Summary: EPA expressed continuing concerns regarding direct, indirect, and cumulative impacts to water quality associated with the contract renewals. EPA requested additional information on water quality degradation in the area, water demand calculations, and methods of water conservation that will be implemented.

ERP No. F–USA–J11020–UT Activities Associated with Future Programs at U.S. Army Dugway Proving Ground, Implementation, Tooele and Jaub Counties, UT.

Summary: No formal comment letter was sent.

ERP No. FB–FTA–L40205–00 South Corridor Project, I–205/Portland Mall Light Rail (Phase I), Selected the Locally Preferred Alternative (LPA), Clackamas and Multnomah Counties, OR.

Summary: No formal comment letter was sent.

ERP No. FS–GSA–G80000–TX Del Rio Port of Entry (POE), Increased Security Measures Associated with Phase II Expansion, Supplement to the 1992 Del Rio Border Patrol Station, Del Rio, Val Verde County, TX.

Summary: EPA has no objections to the proposed project.

Dated: February 1, 2005.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 05–2178 Filed 2–3–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL HOUSING FINANCE BOARD

Sunshine Act Meeting Notice; Announcing a Partially Open Meeting of the Board of Directors

TIME AND DATE: The open meeting of the Board of Directors is scheduled to begin at 10 a.m. on Wednesday, February 9, 2005. The closed portion of the meeting will follow immediately the open portion of the meeting.

PLACE: Board Room, Second Floor, Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006.

STATUS: The first portion of the meeting will be open to the public. The final portion of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED AT THE OPEN PORTION OF THE MEETING:

Capital Plan Amendment for the Federal Home Loan Bank of Dallas.

Final Rule Updating the Minority Contractors Outreach Program.

Proposed Rule Establishing a Data Directive Manual (DDM).

MATTER TO BE CONSIDERED AT THE CLOSED PORTION OF THE MEETING:

Periodic Update of Examination Program Development and Supervisory Findings.

CONTACT PERSON FOR MORE INFORMATION: Shelia Willis, Paralegal Specialist, Office of General Counsel, at (202) 408–2876 or *williss@fhfb.gov.*

Dated: February 2, 2005.

By the Federal Housing Finance Board.

Mark J. Tenhundfeld,

General Counsel.

[FR Doc. 05–2311 Filed 2–2–05; 3:11 pm]

BILLING CODE 6725–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding date shown below:

License Number: 002238N.

Name: CSI Cargo System Air and Sea Inc.

Address: 150–40 183rd Street, Room 106, Jamaica, NY 11413.

Date Revoked: January 8, 2005.

Reason: Failed to maintain a valid bond.

License Number: 000344F.

Name: Godwin Shipping Company Inc.

Address: 317 St. Joseph Street, Mobile, AL 36603.

Date Revoked: January 15, 2005.

Reason: Failed to maintain a valid bond.

License Number: 017952N.

Name: Uniworld Cargo Shipping Lines, LLC.

Address: 4000 West Side Avenue, North Bergen, NJ 07047.

Date Revoked: January 13, 2005.

Reason: Failed to maintain a valid bond.

License Number: 004393F.

Name: Worldserv Transport Corporation.

Address: 12282 Gamma Street, Garden Grove, CA 92840.

Date Revoked: March 17, 2000.

Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 05–2148 Filed 2–3–05; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary license has been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984, as amended by the Ocean Shipping Reform Act of 1998 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/address	Date reissued
004505N	Freight Master Systems, International, Inc., 3760 Guion Road, Indianapolis, IN 46222	December 16, 2004.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 05–2146 Filed 2–3–05; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicant

Notice is hereby given that the following applicant has filed with the Federal Maritime Commission an application for license as a Non-Vessel-Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR part 515).

Persons knowing of any reason why the following applicant should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel-Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicant: Full Package Logistics Inc., 1890 NW 82nd Avenue, Suite 101, Miami, FL 33126. Officers: Manuel A. Lescano, President (Qualifying Individual), Leopoldo del Calvo, Sr., Vice President.

Dated: January 28, 2005.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 05–2147 Filed 2–3–05; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Rescission of Order of Revocation

Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to sections 14 and 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License Number: 018391N.

Name: LCL Cargo Services Inc.

Address: 8100 NW., 29th Street, Miami, FL 33122.

Order Published: FR: 12/22/04 (Volume 69, No. 245, Pg. 76766).

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 05–2149 Filed 2–3–05; 8:45 am]

BILLING CODE 6730–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0200]

General Services Administration Acquisition Regulation; Information Collection; Sealed Bidding

AGENCY: Office of the Chief Acquisition Officer, GSA.

ACTION: Notice of request for comments regarding a renewal to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration has submitted to the Office of Management and Budget (OMB) a request to review and approve a renewal of a currently approved information collection requirement regarding sealed bidding. A request for public comments was published at 69 FR 56769, September 22, 2004. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: March 7, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Zaffos, Procurement Analyst, Contract Policy Division, at telephone (202) 208–6091 or via e-mail to *jerry.zaffos@gsa.gov*.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Ms. Jeanette Thornton, GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to the Regulatory Secretariat (VIR), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090–0200, Sealed Bidding, in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration is requesting that the Office of Management and Budget (OMB) review and approve information collection, 3090–0200, Sealed Bidding. The information requested regarding an offeror's monthly production capability is needed to make progressive awards to ensure coverage of stock items.

B. Annual Reporting Burden

Respondents: 10
Responses Per Respondent: 1
Hours Per Response: .5
Total Burden Hours: 5
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208–7312. Please cite OMB Control No. 3090–0200, Sealed Bidding, in all correspondence.

Dated: January 31, 2005

Julia Wise,

Deputy Director,Contract Policy Division.

[FR Doc. 05–2145 Filed 2–3–05; 8:45 am]

BILLING CODE 6820–61–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Opportunity for Cosponsorship of the President's Challenge Physical Activity and Fitness Awards Program

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of the President's Council on Physical Fitness and Sports.

ACTION: Notice.

SUMMARY: The Office of the President's Council on Physical Fitness and Sports (PCPFS) announces the opportunity for both non-Federal public and private sector entities to cosponsor/administer a series of financially self-sustaining PCPFS activities related to the President's Challenge Physical Activity and Fitness Awards Program. Potential cosponsors must have a demonstrated interest and capability to administer a series of physical activity/fitness and/or sports awards and recognitions and be willing to participate substantively in the cosponsored activity.

DATES: To receive consideration, a request to participate as a cosponsor must be received by the close of business on Friday, April 1, 2005 at the address listed. Requests will meet the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date. Private metered postmarks will not be acceptable as proof of timely mailing. Hand-delivered requests must be received by 5 p.m. Requests that are received after the deadline date will be returned to the sender.

ADDRESSES: Notification of interest and proposal for cosponsorship should be sent to Christine Spain, Director of Research, Planning and Special Projects, Office of the President's Council on Physical Fitness and Sports, Hubert H. Humphrey Building, Room 738–H, 200 Independence Avenue, SW., Washington, DC 20201; Ph: (202) 690–5148, Fax: (202) 690–5211. Notifications and proposals may also be submitted by electronic mail to *cspain@osophs.dhhs.gov*.

FOR FURTHER INFORMATION CONTACT: Christine Spain, Director of Research, Planning and Special Projects, Office of the President's Council on Physical Fitness and Sports, Hubert H. Humphrey Building, Room 738–H, 200 Independence Avenue, SW., Washington, DC 20201; Ph: (202) 690–5148, Fax: (202) 690–5211, E-mail: *cspain@osophs.dhhs.gov*.

SUPPLEMENTARY INFORMATION:

Background

The PCPFS was established by the President of the United States and operates under Executive Order No. 13265, continued by Executive Order 13316. The Secretary, through the Office of the PCPFS, receives recommendations from the Council and is developing and coordinating a national program to enhance physical activity/fitness and sports programs. Section (1)(b) of Executive Order (EO) 13265 provides that the Secretary will ''enhance coordination of programs within and among the private and public sectors that promote participation in, and safe and easy access to, physical activity and sports.'' In addition, the Secretary is directed by section (1)(c) of the EO 13265 to ''expand availability of quality information and guidance regarding physical activity and sports participation.'' Through the authority of section 1704 of the Public Health Service Act, the Office of PCPFS may support and ''encourage others to support'' activities related to physical activity/fitness, sports and health information and promotion, including the publication of information and securing the cooperation of communication media.

The purpose of the President's Challenge Physical Activity and Fitness Awards Program (the Program) is to motivate individuals six years and older to begin and continue an active lifestyle leading to enhanced physical fitness. It has reached over 70 million children and youth since its inception in 1966. The Program now focuses on three distinct program areas: physical fitness, health fitness, and active lifestyles. Adults can now participate with their children or log activities by themselves to earn the Presidential Active Lifestyle Award (PALA) and the Presidential Champions Program. Program materials are available in both English and Spanish.

Requirements of Cosponsorship

The Office of the PCPFS is seeking a cosponsoring organization(s) capable of administering a series of financially self sustaining PCPFS awards which presently include the following: Administration of the President's Challenge shall consist of the following program areas:

A. Active Lifestyle Program

Presidential Active Lifestyle Award (PALA)

Recognizing both youth and adults for being physically active on a regular basis. Participants are encouraged to keep track of their physical activity either with a paper log or by using online tools.

B. Presidential Champions Program

Gold, Silver, Bronze Awards

This program is a point-based program for both youth and adults recognizing those who are physically active on a regular basis and log their activities online. This program is only available online at *http://www.presidentschallenge.org*.

C. Physical Fitness Program

Presidential Physical Fitness Award (PPFA)

Recognizing youth for achieving an outstanding level of physical fitness based on a five-item test.

National Physical Fitness Award (NPFA)

Recognizing youth for achieving a basic, yet challenging, level of physical fitness based on a five-item test.

Participant Award

Recognizing those who attempt all five test items, but fall below the National Award level in one or more events

D. Health Fitness Program

Health Fitness Award

Recognizing youth who achieve a healthy level of fitness based on five test items, including Body Mass Index (BMI).

E. School Recognition Programs

Physical Fitness State Champion Program

Based on results of the Physical Fitness Program, schools are recognized for having the highest percentage of Presidential Physical Fitness Award winners for their state. States are broken into three categories based upon enrollment (minimum 50 students).

Physical Activity and Fitness Demonstration Center Program

Recognizing the important role that individual schools play in the lives of their students, this program rewards those schools that have demonstrated an outstanding commitment toward physical activity and fitness both in and out of their physical education classroom. Demonstration Center Schools shall serve a term of three years before becoming eligible to become an Honor Roll School.

Active Lifestyle Model School Program

Based on the results of the Active Lifestyle Program and objectives of Healthy People 2010, this program offers any school the opportunity to become an Active Lifestyle Model School. Model Schools are recognized for having 35% or more of their total school enrollment earn the PALA two or more times during the school year.

Each of these program areas shall involve the promotion and distribution of award items. These items shall include, but not be limited to, such products as emblems, medallions, ribbons, lapel pins, certificates, bumper stickers, magnets, booklets, pedometers, and apparel. Organizations (schools, youth and community groups, etc.) and individuals which participate in the PCPFS awards program purchase the award and recognition materials directly from the administering organization for a nominal fee.

Web Site Administration

Administration of the President's Challenge Web site (*http://www.presidentschallenge.org*) shall consist of, but not be limited to, the following: hosting, maintenance, customer service, online order center, listservs, etc.

Eligibility for Cosponsorship

To be eligible, a requester must: (1) Have a demonstrated interest and understanding of physical fitness and/or sports; (2) participate substantively in the cosponsored activity (not just provide funding or logistical support); (3) have an organizational or corporate mission that is not inconsistent with the public health and safety mission of the Department; and (4) agree to sign a cosponsorship agreement with the Office of the PCPFS which will set forth the details of the cosponsored activity including the requirements that any fees raised should not be designed to exceed the co-sponsor's costs, and fees collected by the co-sponsor should be limited to the amount necessary to cover the co-sponsor's related operating expenses.

Cosponsorship Proposal

Each cosponsorship proposal should contain a description of: (1) The entity or organization; (2) its background in promoting physical activity/fitness or sports; (3) its proposed involvement in the cosponsored activity; and (4) plan for implementation with timeline. The organization selected shall furnish the necessary personnel, materials, services and facilities to administer this PCPFS program (awards, recognitions and activities), including the purchase and/or production of all award materials; distribution of award materials; promotion; statistical evaluation of programs; quarterly and annual budget and demographic reports; and other administrative duties. These duties will be determined in a Memorandum of Agreement and an annual plan. The organization will be expected to provide input regarding new activities or initiatives to support the program, and recommend methods to improve program usage and promotion. The organization also will work with the PCPFS to consider other recognitions/programs bearing the PCPFS and/or Presidential insignias.

Evaluation Criteria

The cosponsor(s) will be selected by the Office of the PCPFS using the following evaluation criteria:

(1) Requester's qualifications and capability to fulfill cosponsorship responsibilities;

(2) Requester's creativity for enhancing the medium for program messages;

(3) Requester's potential for reaching underserved/special populations;

(4) Requester's experience in administering national awards programs;

(5) Requester's specific work previously performed or currently being performed, with particular emphasis on those national programs/projects dealing with physical activity/fitness, sports, or other physical activities of a similar nature, with schools, organizations, and individuals;

(6) Requester's personnel: Name, professional qualifications and specific experience of key personnel who would be available to work on these projects;

(7) Requester's facilities: Availability and description of facilities required to administer the program including information technology, computers, telecommunication resources;

(8) Requester's description of financial management: Discussion of experience in developing an annual budget and collecting and managing monies from organizations and/or individuals;

(9) Requester's proposed plan for managing the PCPFS awards programs, including such financial aspects as cost of award materials, promotion, distribution and program management.

Availability of Funds

There are no Federal funds available for this cosponsorship.

Dated: January 31, 2005.

Melissa Johnson,

Executive Director, President's Council on Physical Fitness and Sports, Department of Health and Human Services.

[FR Doc. 05–2163 Filed 2–3–05; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92–463, notice is hereby given of the sixth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to 5:30 p.m. on February 28, 2005 and 8:30 a.m. to 5 p.m. on March 1, 2005 at the Bethesda North Marriott Hotel, 5701 Marinelli Road, North Bethesda, Maryland. The meeting will be open to the public with attendance limited to space available. The meeting will be webcast.

The meeting is expected to include presentations and deliberations on several topics, including the following: a revised draft report with recommendations about coverage and reimbursement for genetic technologies and services; current and proposed efforts to understand gene-environment interactions through large population studies; the Committee's efforts to explore stakeholder perspectives on the need for Federal legislation to prevent genetic discrimination in health insurance and employment; the recommendations of the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children regarding the provision of screening, counseling and health care services for newborns and children having or at risk for heritable disorders; and efforts to improve the quality of laboratory testing for rare diseases. Time will be provided each day for public comments.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the board range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the webcast, will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm.*

The Committee would welcome hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or e-mail at *sc112c@nih.gov.* The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Dated: January 27, 2005.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–2129 Filed 2–3–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–0576]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 371–5976. CDC is requesting an emergency clearance from OMB regarding this data collection with a 10 day public comment period. The emergency clearance is based on a revision of this data collection as a result of a final rule.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 371–5976 or send an e-mail to *omb@cdc.gov.* Written comments can be sent to Seleda M. Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or sent via e-mail to *omb@cdc.gov.* Written comments can also be faxed to the CDC Desk Officer, Human Resources and Housing Branch, Office of Management and Budget at (202) 395–6974. Written comments should be received within 10 days of this notice.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576)—Extension—Office of the Director (OD), Centers for Disease Control and Prevention (CDC).

The Public Health Security and Bioterrorism Preparedness and

Response Act of 2002 (Pub. L. 107–188) specifies that the Secretary of Health and Human Services shall provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of select biological agents and toxins. The Act specifies that facilities that possess, use, and transfer select agents register with the Secretary. The Secretary has designated CDC as the agency responsible for collecting this information.

CDC is requesting an emergency clearance to allow the continued collection of this information through the use of five separate forms. These forms have been revised since the last clearance. This emergency request will allow CDC to use the revised forms. These forms are: (1) Application for Registration, (2) Transfer of Select Agent or Toxin Form, (3) Facility Notification of Theft, Loss, or Release Form, (4) Clinical and Diagnostic Laboratory Reporting Form, and (5) Request for Exemption.

The Application for Registration (42 CFR 73.7(d)) will be used by entities to register with CDC. The Application for Registration requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information. Estimated average time to complete this form is 3 hours, 45 minutes for an entity with one principal investigator working with one select agent or toxin. CDC estimates that entities will need an additional 45 minutes for each additional investigator or agent. In our regulatory analysis, we have estimated that 70% of the 350 entities have 1–3 principal investigators, 15% have 5 principal investigators, and 15% have 10 principal investigators. We have used these figures to calculate the burden for this section. The revisions to this form were administrative in nature. Estimated burden for the Application for Registration is 2,191 hours.

Entities may amend their registration (42 CFR, 73.7(h)(1)) if any changes occur in the information submitted to the HHS Secretary. To apply for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to CDC. Estimated time to amend a registration package is 1 hour.

The Facility Notification Form (42 CFR 73.19(a), (b)) must be completed by entities whenever there is theft, loss, or release of a select agent or toxin. In the revised rules we are now requiring reporting from exempt entities. Estimated average time to complete this form is 1 hour.

The Request for Exemption form (42 CFR 73.5 (d), (e) and 73.6 (d), (e)) will be used by entities that are using select agents or toxins in investigational new drug testing or in cases of public health emergency. The revisions to this form were administrative in nature. Estimated average time to complete this form is 1 hour.

The Transfer of Select Agent or Toxin Form (42 CFR 73.16) will be used by entities requesting transfer of a select agent or toxin to their facility and by the entity transferring the agent. CDC revised the Transfer of Select Agent or Toxin Form by removing the requirement that entities provide written notice within five business days when select agents or toxins are consumed or destroyed after a transfer. Estimated average time to complete this form is 1 hour, 30 minutes.

The Clinical and Diagnostic Laboratory Exemption Report (42 CFR 73.5(a), (b) and 73.6(a), (b)) will be used by clinical and diagnostic laboratories to notify the HHS Secretary that select agents or toxins identified as the result of diagnostic or proficiency testing have been disposed of in a proper manner. In the revised form revisions were made to clarify that the registered entities required to report can now retain the agent. Estimated average time to complete this form is 1 hour.

In addition to the standardized forms, this regulation also outlines situations in which an entity must notify or may make a request of the HHS Secretary in writing. An entity may apply to the HHS Secretary for an expedited review of an individual (*e.g.* Principal Investigator) by the Attorney General (42 CFR 73.10(e)). To apply for this expedited review, an entity must submit a request in writing to the HHS Secretary establishing the need for such action. The estimated time to gather the information and submit this request is 30 minutes. CDC has not developed standardized forms to use in the above situations. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

An entity may also apply to the HHS Secretary for an exclusion of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e)(1) and 73.4(e)(1)). The estimated time to gather the information and submit this request is 1 hour.

As part of the requirements of the Responsible Official, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents or toxins are stored. Results of these self-inspections must be documented (42 CFR 73.9(a)(5)). CDC estimates, that, on average, such documentation will take 1 hour.

As part of the training requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training (42 CFR 73.15(c)). Estimated time for this documentation is 2 hours per principal investigator.

An entity or an individual may request administrative review of a decision denying or revoking certification of registration (42 CFR 73.20). This request must be made in writing and within 30 calendar days after the adverse decision. This request should include a statement of the factual basis for the review. CDC estimates the time to prepare and submit such a request is 4 hours.

Finally, an entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified (42 CFR 73.17). The time to implement such a system is estimated to average 4 hours.

The cost to respondents is their time to complete the forms and comply with the reporting and recordkeeping components of the Act plus a one-time purchase of a file cabinet (estimated cost $400) to maintain records.

Annualized Burden Hours:

CFR reference	Data collection	Number of respondents	Responses per respondent	Average hourly burden	Total annual burden (in hours)
73.7(d)	Registration Application	350	1	3.75	1,313
73.7(d)	Additional Investigators	245	2	45/60	368
73.7(d)	Additional Investigators	53	4	45/60	159
73.7(d)	Additional Investigators	52	9	45/60	351

CFR reference	Data collection	Number of respondents	Responses per respondent	Average hourly burden	Total annual burden (in hours)
73.7(h)(1)	Amendment to Registration Application.	350	2	1	700
73.19(a)(b)	Notification Form	12	1	1	12
73.5 & 73.6 (d-e)/73.3 & 73.4(e)(1)	Request for Exemption/Exclusion	17	1	1	17
73.16	Transfer of Select Agent or Toxin	350	2	90/60	1,050
73.5 & 73.6(a)(b)	Clinical and Diagnostic Laboratory Exemption Report.	325	4	1	1,300
73.10(e)	Request expedited review	10	1	30/60	5
73.9(a)(5)	Documentation of self-inspection	350	1	1	350
73.15(c)	Documentation of training	350	1	2	700
73.20	Administrative Review	15	1	4	60
73.17	Ensure secure recordkeeping system.	350	1	4	1,400
Total					7,785

Dated: January 31, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–2144 Filed 2–3–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Board of Scientific Counselors, National Center for Health Statistics, Centers for Disease Control and Prevention, of the Department of Health and Human Services, has been renewed for a 2-year period through January 19, 2007.

For information, contact Robert J. Weinzimer, Executive Secretary, Board of Scientific Counselors, National Center for Health Statistics, Centers for Disease Control and Prevention, of the Department of Health and Human Services, Metro III, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/458–4565 or fax 301/458–4025.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 28, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–2140 Filed 2–3–05; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Guide to Community Preventive Services (GCPS) Task Force

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Task Force on Community Preventive Services.

Times and Dates: 8 a.m.–7 p.m., February 16, 2005. 8 a.m.–1 p.m., February 17, 2005.

Place: The Hyatt Regency Atlanta, 265 Peachtree Street, Atlanta, Georgia 30303–1294, telephone (404) 577–1234.

Status: Open to the public, limited only by the space available.

Purpose: The mission of the Task Force is to develop and publish a Guide to Community Preventive Services, which is based on the best available scientific evidence and current expertise regarding essential public health and what works in the delivery of those services.

Matters To Be Discussed: Agenda items include: briefings on administrative information, release of the Community Guide book, dissemination of Community Guide findings and the book, work with the Campbell and Cochrane Collaborations, using reviews conducted by external groups to support Community Guide recommendations, update on collaborative review of HIV risk reduction for men who have sex with men (MSM), possible recommendations for HIV partner counseling and referral services (PCRS), reducing the harmful consequences of trauma among juveniles, one-on-one interventions and multi-component media to increase cancer screening, culturally competent health care systems, update and finalizing of recommendation outcomes for the alcohol reviews.

Agenda items are subject to change as priorities dictate.

Persons interested in reserving a space for this meeting should call 404/498–6180 by close of business on February 9, 2005.

Contact Person or Additional Information: Peter Briss, M.D., Chief, Community Guide Branch, Coordinating Center for Health Information and Service, National Center for Health Marking, Division of Prevention Research, 1600 Clifton Road, M/S E–90, Atlanta, GA 30333 (404) 498–6180.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 31, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–2143 Filed 2–3–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3155–N]

RIN 0938–AN67

Medicare Program; Quality Improvement Organization Contracts: Solicitation of Statements of Interest From In-State Organizations—Alaska, Hawaii, Idaho, Maine, South Carolina, Vermont, and Wyoming

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with Section 1153(i) of the Social Security Act, gives at least 6-months' advance notice of the expiration dates of contracts with out-of-State Utilization and Quality Control Peer Review Organizations. It also specifies the period of time in which in-State organizations may submit a statement of interest so that they may be eligible to compete for these contracts.

DATES: Written statements of interest must be received at the address specified no later than 5 p.m. EST February 22, 2005. Due to staffing and resource limitations, we cannot accept statements submitted by facsimile (FAX) transmission.

ADDRESSES: Statements of interest must be submitted to the Centers for Medicare & Medicaid Services, Acquisitions and Grants Groups, OOM, Attn.: Carol G. Sevel, 7500 Security Boulevard, Mail Stop C2–21–15, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: Udo Nwachukwu, (410) 786–7234.

SUPPLEMENTARY INFORMATION:

I. Background

The Peer Review Improvement Act of 1982 (Title I, subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248) amended Part B of Title XI of the Social Security Act (the Act) by establishing the Utilization and Quality Control Peer Review Organization program.

Utilization and Quality Control Peer Review Organizations, now known as Quality Improvement Organizations (QIOs), currently review certain health care services furnished under Title XVIII of the Act (Medicare) and certain other Federal programs to determine whether those services are reasonable, medically necessary, provided in the appropriate setting, and are of a quality that meet professionally recognized standards. QIO activities are a part of the Health Care Quality Improvement Program (HCQIP), a program that supports our mission to ensure health care security for our beneficiaries. The HCQIP rests on the belief that a plan's, provider's, or practitioner's own internal quality management system is key to good performance. The HCQIP is carried out locally by the QIO in each State. Under the HCQIP, QIOs provide critical tools (for example, quality indicators and information) for plans, providers, and practitioners to improve the quality of care provided to Medicare beneficiaries. The Congress created the QIO program in part to redirect, simplify, and enhance the cost-effectiveness and efficiency of the peer review process.

In June 1984, we began awarding contracts to QIOs. We currently maintain 53 QIO contracts with organizations that provide medical review activities for the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. The organizations that are eligible to contract as QIOs have satisfactorily demonstrated that they are either physician-sponsored or physician-access organizations in accordance with sections 1152 and 1153 of the Act and our regulations at 42 CFR 475.102 and 475.103. A physician-sponsored organization is one that is both composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the respective review area and who are representative of the physicians practicing in the review area. A physician-access organization is one that has available to it, by arrangement, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to ensure adequate peer review of the services furnished by the various medical specialties and subspecialties. In addition, the organization must not be a health care facility, health care facility association, a health care facility affiliate, or in most cases a payor organization. (Statutes and regulations provide that, in the event CMS determines no otherwise qualified non-payor organization is available to undertake a given QIO contract, CMS may select a payor organization which otherwise meets requirements to conduct QIO Utilization and Quality Control Peer Review as specified in Part B of Title XI of the Social Security Act and implementing regulations.) The selected organization must have a consumer representative on its governing board.

The Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) amended section 1153 of the Act by adding new paragraph (i) that prohibits us from renewing the contract of any QIO that is not an in-State organization without first publishing in the **Federal Register** a notice announcing when the contract will expire. This notice must be published no later than 6-months before the date the contract expires and must specify the period of time during which an in-State organization may submit a proposal for the contract. If one or more qualified in-State organizations submit a proposal within the specified period of time, we cannot automatically renew the contract on a noncompetitive basis, but must instead provide for competition for the contract in the same manner used for a new contract. An in-State organization is defined as an organization that has its primary place of business in the State in which review will be conducted (or, that is owned by a parent corporation, the headquarters of which is located in that State).

There are currently 7 QIO contracts with entities that do not meet the statutory definition of an in-State organization. The areas affected for purposes of this notice along with their respective expiration dates are as follows: Vermont, July 31, 2005; Wyoming, July 31, 2005; Maine, July 31, 2005; Alaska, October 31, 2005; Idaho, October 31, 2005; Hawaii, January 31, 2006; South Carolina, January 31, 2006.

II. Provisions of the Notice

This notice announces the scheduled expiration dates of the current contracts between CMS and out-of-State QIOs responsible for review in the areas mentioned above.

Interested in-State organizations may submit statements of interest in competing to become the QIO for these States. We must receive the statements no later than February 22, 2005, and in its statement of interest, the organization must furnish materials that demonstrate that it meets the definition of an in-State organization. Specifically, the organization must have its primary place of business in the State in which review will be conducted or be a subsidiary of a parent corporation, whose headquarters is located in that State. In its statement, each interested organization must further demonstrate that it meets the following requirements:

A. Be Either a Physician-Sponsored or a Physician-Access Organization

1. Physician-Sponsored Organization

To be eligible as a physician-sponsored organization, the

organization must meet the following requirements:

a. Be composed (have physicians as owners or members) of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the State (that is, at least 20 percent of the practicing physicians in the State are owners of the QIO, or the QIO is owned by an entity which includes at least 20 percent of the practicing physicians in the State as members); or

b. Be composed (have physicians as owners or members) of at least 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the State, and demonstrate through means (for example, letters of support from physicians or physician organizations) acceptable to CMS that the organization is representative of an additional 10 percent of the practicing physicians in the State; and

c. Not be a health care facility, health care facility association, or health care facility affiliate.

2. Physician-Access Organization

To be eligible as a physician-access organization, the organization must meet the following requirements:

a. Have arrangements with doctors of medicine or osteopathy, licensed and practicing in the State, to conduct review for the organization;

b. Have available at least one physician, licensed in the State, from every generally recognized specialty and subspecialty who is in active practice in the review area; and

c. Not be a health care facility, health care facility association, or health care facility affiliate.

B. Have at Least One Individual Who Is a Representative of Consumers on Its Governing Board

If one or more organizations meet the above requirements in one of the 7 QIO areas in this notice and submit statements of interest in accordance with this notice, we will consider those organizations to be potential sources for contract upon its expiration. These organizations will be entitled to participate in a full and open competition for the QIO contract to perform the QIO statement of work.

III. Information Collection Requirements

This notice contains information collection requirements that have been approved by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and assigned OMB Control Number 0938–0526 entitled ''Quality Improvement (formerly Peer Review) Organization, Contracts: Solicitation of Statements of Interest from In-State Organization, General Notice and Supporting Regulations.''

Authority: Section 1153 of the Social Security Act (42 U.S.C. 1320c-2).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: January 26, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–1878 Filed 1–27–05; 5:06 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1299–N]

Medicare Program; Monthly Payment Amounts for Oxygen and Oxygen Equipment for 2005, in Accordance with Section 302(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice discusses a reduction in the 2005 monthly payment amounts for oxygen and oxygen equipment based on the percentage difference between Medicare's 2002 monthly payment amounts for each State and the median 2002 Federal Employee Health Benefit plan price reported by the Office of Inspector General. This reduction is required by section 302(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 786–4499, *jkaiser@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 302(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003), Medicare's monthly payment amounts for oxygen and oxygen equipment for 2005 are to include a reduction based on the percentage difference between Medicare's 2002 monthly payment amounts for each State and the median 2002 Federal Employee Health Benefit (FEHB) plan price reported by the Office of Inspector General (OIG). The OIG has alerted us that they will need to collect additional information before the FEHB medians for oxygen and oxygen equipment and portable oxygen equipment are finalized. Therefore, Medicare claims for oxygen and oxygen equipment and portable oxygen equipment furnished on or after January 1, 2005, and identified by the Healthcare Common Procedure Coding System codes listed below, will be temporarily paid based on the 2004 monthly payment amounts. In accordance with the authority provided by section 1871(e)(1)(A)(ii) of the Social Security Act, we are making this change retroactive for items and services furnished on or after January 1, 2005, because we have determined that it would be contrary to the public interest to implement 2005 payment amounts based on preliminary and potentially erroneous data.

- E0424—Stationary Compressed Gaseous Oxygen System, Rental: Includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing;
- E0439—Stationary Liquid Oxygen System, Rental: Includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing;
- E1390—Oxygen Concentrator, Single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate;
- E1391—Oxygen Concentrator, Dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate;
- E0431—Portable Gaseous Oxygen System, Rental: Includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing;
- E0434—Portable Liquid Oxygen System, Rental: Includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing.

Once we receive the FEHB medians from the OIG, we will calculate and implement the 2005 monthly payment amounts and will begin paying claims using these amounts. These amounts will apply prospectively only. This is explained at *http://www.cms.hhs.gov/suppliers/dmepos/.* Any future updates will also be published at this website.

II. Provisions of the Notice

The purpose of this notice is to notify the public that the OIG has informed us of their need for additional information before the provision may be used and implemented to reduce monthly payment amounts for oxygen and oxygen equipment, based on the percentage difference between Medicare's 2002 monthly payment amounts for each State and the median 2002 Federal Employee Health Benefit plan price reported by the OIG.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Statement

We have examined the impact of this notice 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.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This notice does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this notice will not have a significant economic impact on a substantial number of small entities. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice will have no consequential effect on the governments mentioned or on the private sector.

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. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this document was not reviewed by the Office of Management and Budget.

Authority: Section 302(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare-Supplemental Medical Insurance Program)

Dated: January 19, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–2176 Filed 2–3–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1366–N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council—March 7, 2005

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council (the Council). The Council will be meeting to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary of the Department of Health and Human Services (the Secretary). This meeting is open to the public.

DATES: The meeting is scheduled for Monday, March 7, 2005, from 8:30 a.m. until 5 p.m. e.s.t.

ADDRESSES: The meeting will be held in Room 705A 7th floor, in the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Meeting Registration: Persons wishing to attend this meeting must contact John P. Lanigan, the Designated Federal Official (DFO) by e-mail at *JLanigan@cms.hhs.gov* or by telephone at (410) 786–2312, at least 72 hours in advance of the meeting to register. Persons not registered in advance will not be permitted to enter the Hubert H. Humphrey Building and will not be permitted to attend the Council meeting. Persons attending the meeting will be required to show a photographic identification, preferably a valid driver's license, before entering the building.

FOR FURTHER INFORMATION CONTACT: Kenneth Simon, M.D., Executive Director, Practicing Physicians Advisory Council, 7500 Security Blvd., Mail Stop C4–10–07, Baltimore, MD, 21244–1850, telephone (410) 786–2312,or e-mail *Ksimon@cms.hhs.gov.* News media representatives must contact the CMS Press Office, (202) 690–6145. Please refer to the CMS Advisory Committees Information Line (1–877–449–5659 toll free)/(410)786–9379 local) or the Internet at *http://www.cms.hhs.gov/faca/ppac/default.asp* for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION: The Secretary is mandated by section 1868(a) of the Social Security Act (the

Act) to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services no later than December 31st of each year.

The Council consists of 15 physicians, each of whom must have submitted at least 250 claims for physicians' services under Medicare in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members of the Council must be physicians as described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists and chiropractors. Members serve for overlapping 4-year terms; terms of more than 2 years are contingent upon the renewal of the Council by appropriate action prior to its termination. Section 1868(a)(1) of the Act provides that nominations to the Secretary for Council membership must be made by medical organizations representing physicians.

The Council held its first meeting on May 11, 1992. The current members are—Jose Azocar, M.D.; James Bergeron, M.D.; Ronald Castellanos, M.D.; Rebecca Gaughan, M.D.; Peter Grimm, D.O.; Carlos R. Hamilton, M.D.; Dennis K. Iglar, M.D.; Joe Johnson, D.C.; Christopher Leggett, M.D.; Barbara McAneny, M.D.; Geraldine O'Shea, D.O.; Laura B. Powers, M.D.; Michael T. Rapp, M.D. (Chairperson); Anthony Senagore, M.D.; and Robert L. Urata, M.D.

The meeting will commence with the swearing-in of three Council members. The Council's Executive Director will give a status report and the CMS responses to the recommendations made by the Council at the November 22, 2004 meeting and prior meeting recommendations. Additionally, updates will be provided on the CMS Report to the Congress on Contractor Reform, and the Physician Regulatory Issues Team. In accordance with the Council charter, CMS is requesting assistance with the following agenda topics:

- Pay for Performance Initiatives.
- Competitive Bidding on Drugs.
- Physician Regulation Proposed Rule; and
- Medicare Prescription Drug Benefit: CMS' Physician Education Plan.

For additional information and clarification on these topics, contact the Executive Director, listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to make a 5-minute oral presentation on agenda issues must contact the Executive Director by 12 noon (e.s.t.) on February 18, 2005, to be scheduled. Testimony is limited to agenda topics only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to John P. Lanigan, Designated Federal Official (DFO), no later than 12 noon (e.s.t) on February 18, 2005, for distribution to Council members for review prior to the meeting. Physicians and medical organizations not scheduled to speak may also submit written comments to the DFO for distribution at the same times as listed for oral presentations. The meeting is open to the public, but attendance is limited to the space available.

Special Accommodations: Individuals requiring sign language interpretation or other special accommodation must contact John P. Lanigan by e-mail at *JLanigan@cms.hhs.gov* or by telephone at (410) 786–2312 at least 10 days before the meeting.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a).)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 31, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–2175 Filed 2–3–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Conference Grants to Support State Food Safety Task Force Meetings; Availability of Funds Grants; Request for Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is correcting notice document 04–14395 beginning on page 35651 in the issue of Friday, June 25, 2004, by making the following corrections:

On page 35651 in the second column, the **DATES** section is corrected to read: ''**DATES:** The application receipt date for new applications is March 15, 2005. The application receipt date for new applications for each subsequent year this program is in effect will be March 15.''

On page 35651, in the second column, the ''**ADDRESSES**'' section should read: ''**ADDRESSES**: FDA is accepting new applications for this program electronically via Grants.gov.; applicants are strongly encouraged to apply electronically by visiting the Web site *http://www.grants.gov*. and following the instructions under ''APPLY.'' The applicant must register in the Central Contractor Registration (CCR) database in order to be able to submit the application.''

Information about CCR is available at *http://www.grants.gov/CCRRegister*. The applicant must register with the Credential Provider for Grants.gov.

Information about this requirement is available at *http://www.grants.gov/CredentialProvider*. If it is necessary for applicants to submit applications other than through the electronic process, application forms are available from, and completed applications should be submitted to Michelle Caraffa, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7025, e-mail: *mcaraffa@oc.fda.gov*. Application forms PHS 5161–1 are available via the Internet at: *http://www.psc.gov/forms* (Revised 7/00). Applications handcarried or commercially delivered should be addressed to 5630 Fishers Lane (HFA–500), rm. 2129, Rockville, MD 20857. An application not received in time for orderly processing will be returned to the applicant without consideration.

On page 35651, beginning in the second column, ''**FOR FURTHER INFORMATION CONTACT**'' should read:

FOR FURTHER INFORMATION CONTACT:
Regarding the administrative and financial management aspects of this notice: Michelle N. Caraffa (see **ADDRESSES**).
Regarding the programmatic aspects of this notice: Stephen Toigo, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs, Food and Drug Administration (HFC–150), 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, or access the Internet at: *http://www.fda.gov/ora/fed_state/default.htm*. For general ORA program information contact your Regional Food Specialists at *http://www.fda.gov/ora/fed_state/DFSR_Activities/food_specialists.htm*

On page 35653 in the first column, under section V.A, a sentence is added at the end of the paragraph that reads: ''A Current Listing of SPOCs can be found at *http://www.whitehouse.gov/omb/grants/spoc.html*.''

On page 35653 in the third column, under section VII, the paragraph is revised to read: ''Applicants are encouraged to apply electronically (see **ADDRESSES**). If not, the original and two copies of the completed grant application Form PHS–5161–1 (Revised 7/00) for State and local governments should be delivered to the Grants Management Office. The receipt date is March 15, 2005. No supplemental material or addenda will be accepted after the receipt date.''

On page 35653 in the third column, under section VIII.A in the second paragraph, the last sentence should read: ''FDA is now accepting applications via the Internet.''

Dated: January 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2209 Filed 2–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 3, 2005, from 8 a.m. to 5 p.m. and March 4, 2005, from 8 a.m. to 1 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 3, 2005, the committee will do the following: (1) Discuss new drug application (NDA) 21–115, COMBIDEX (ferumoxtran–10), Advanced Magnetics, Inc., proposed indication for intravenous administration as a magnetic resonance imaging contrast agent to assist in the differentiation of metastatic and nonmetastatic lymph nodes in patients with confirmed primary cancer who are at risk for lymph node metastases, and (2) discuss prostate cancer endpoints as a followup to the June 2004 FDA workshop. On March 4, 2005, the committee will do the following: (1) Discuss the results of a confirmatory trial for NDA 21–399, IRESSA (gefitinib) AstraZeneca Pharmaceticals LP, for the treatment of patients with locally advanced or metastatic nonsmall cell lung cancer after failure of both platinum-based and docetaxel chemotherapies, and (2) discuss safety concerns, specifically osteonecrosis of the jaw (ONJ), associated with two bisphosphonates, NDA 21–223, ZOMETA (zoledronic acid) Injection and AREDIA (pamidronate disodium for injection), both from Novartis Pharmaceuticals Corp. ZOMETA is indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy. It is also approved for hypercalcemia of malignancy. AREDIA is indicated, in conjunction with standard antineoplastic therapy, for the treatment of osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma. It is also indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, and treatment of patients with moderate to severe Paget's disease of bone.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 28, 2005. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 2:30 p.m. to 3 p.m. on March 3, 2005, and between approximately 10:30 a.m. to 11 a.m. on March 4, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Trevelin Prysock at 301–827–7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 27, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–2208 Filed 2–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Development of Revised Need for Assistance Criteria for Assessing Community Need for Comprehensive Primary and Preventive Health Care Services Under the President's Health Centers Initiative

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Solicitation of comments.

SUMMARY: Currently, application scores for New Access Point (NAP) applications under the President's Health Centers Initiative (Program) cluster at the high end of the scoring range, providing little distinction among applicants. Since the intent of the Program is to provide grants to the neediest communities, HRSA is considering placing more emphasis on assessing the need for comprehensive primary and preventive health care services in the service area or for the population for which the applicant is seeking support, by revising the Need for Assistance Criteria and changing the relative weights of the review criteria used in evaluating such applications. This notice offers public and private nonprofit entities an opportunity to comment on the proposed changes in the Need for Assistance Criteria (NFA), and on the degree to which need should be weighted relative to other criteria used in evaluating future applications. In order to solicit comments from the public on these proposed changes, HRSA is delaying the due date (May 23, 2005) for the second round of fiscal year (FY) 2005 New Access Point applications.

Authorizing Legislation: Section 330(e)(1)(A) of the Public Health Service Act, as amended, authorizes support for the operation of public and nonprofit private health centers that provide health services to medically underserved populations.

Reference: For the current Need for Assistance (NFA) criteria and other application review criteria, including weights used most recently, see Program Information Notice (PIN) 2005–01, titled ARequirements of Fiscal Year 2005 Funding Opportunity for Health Center New Access Point Grant Applications,'' are available on HRSA's Bureau of Primary Health Care (BPHC) Web site at *http://bphc.hrsa.gov/pinspals/pins.htm.* That PIN detailed the eligibility requirements, review criteria, and awarding factors for applicants seeking support for the operation of New Access Points in FY 2005.

Background: The goal of the President's Health Centers Initiative, which began in FY 2002, is to increase access to comprehensive primary and preventive health care services to 1,200 of the Nation's neediest communities through new and/or significantly expanded health center access points over five years. These health center access points are to provide comprehensive primary and preventive health care services in areas of high need that will improve the health status of the medically underserved populations to be served and decrease health disparities. Services at these new access points may be targeted toward an entire community or service area or toward a specific population group in the service area that has been identified as having unique and significant barriers to affordable and accessible health care services.

While it is extremely important that NAP grant awards be made to entities that will successfully implement a viable and compliant program for the delivery of comprehensive primary health services to the populations or communities they propose to serve, HRSA also needs to assure that all applicants seeking support for a NAP applicant can demonstrate the need for such services in the community (area or population group) to be served and be evaluated on that need. Under the current guidance, NFA criteria are used to quantify barriers to access and identify health disparities. The NFA process also establishes a threshold which applicants must meet in order for their applications to be reviewed by the Objective Review Committee (ORC).

Description of Current NFA process. The current NFA process (as described in Form 9-Part A of PIN 2005–01) involves two major groups of indicators. First, from eight (8) ''Barriers and Access to Care'' measures, the applicant must select five (5). These measures are: Shortage of primary care physicians, as measured by whether the target service area has been designated as a geographic or population group Health Professions Shortage Area (HPSA); Percent of the population with incomes below 200% of the Federal poverty level; Life expectancy of target population (in years); percentage of target population uninsured; unemployment rate of target population; average travel time or distance to nearest source of primary care for target population; percentage of target population age 5 or older who speak a language other than English at home; and length of waiting time for public housing and Section 8 certificates for target population. For the first of these measures, the applicant receives 14 points if HPSA-designated and zero otherwise; for each of the other measures, the NFA criteria define a 6-level scale from 0 to 14 points. The applicant provides data for its service area or target population for each of the 5 measures selected, and identifies the source of data used. Given 5 indicators and a maximum of 14 points for each, there are a possible 70 points for the ''Barriers and Access to Care'' indicators.

Second, from 28 ''Health Disparity Factors'', the applicant selects 10 and provides data on each for its service areas or target populations. For each factor selected, the applicant can receive 3 points if the value for the target population exceeds the benchmark used. The applicant defines the benchmark, and gives a source for that benchmark as well as a source for the target population data provided. The guidance lists 27 specific factors, plus an ''other'' category allowing the applicant to select one additional locally-relevant factor not anticipated by the guidance. This approach produces a possible 30 points for the ''Health Disparities Factors'' section; combined with the possible 70 for ''Barriers and Access to Care'' section, allowing a possible 100 total points are possible. In current guidance, the threshold for having the application reviewed has been set at an NFA score of 70 out of the possible 100 total points.

Need for Assistance Worksheets and the Application Review Process

In accordance with the guidance, all applicants are required to complete an NFA Worksheet, identifying the NFA indicators they have selected from the options available and providing the data on these indicators for their proposed service area or target population. The Worksheet is reviewed by an Objective Review Committee (ORC), and only those applicants that achieve a score of 70 or higher out of the possible 100 points have the merits of their application evaluated by the ORC. To date, under the President's Initiative, HRSA has found that most applicants achieve the minimum of 70 NFA points required in the current process for consideration of their application. Furthermore, under the current application review process, only 10% of the total (100) possible points are allocated to the applicant's description of the need for additional primary care services in the community or target population to be served. Currently, application scores cluster at the high end of the scoring range, providing little discrimination among applications.

For these reasons, HRSA arranged for an external evaluation of the NFA criteria and the use of need factors in the overall application review process. (The evaluation was conducted by a team of HSR, Inc., and the University of North Carolina's Cecil G. Sheps Center for Health Services Research.) Key results of the evaluation analyses are presented below, followed by recommendations for proposed changes on which we are soliciting comments.

Current NFA Access Barriers—Frequency of Applicant Use; Scores Achieved

An analysis of applications received during FY 2004 indicated that, with respect to the eight ''Barriers and Access to Care'' indicators, 92% of applicants selected the indicator percent of target population below 200% poverty; 79% selected percent of target population uninsured; 78% selected shortage of primary care physicians; and 75% selected unemployment rate for the target population, while only 36% selected life expectancy of the target population and 34% selected travel time or distance. Language other than English and shortage of Public Housing were selected by 55% and 50% of the applicants respectively. Since applicants naturally chose the variables that gave them the highest scores, the average scores achieved on all of the ''Barriers and Access to Care'' indicators ranged from 12 to 14 for each, except for life expectancy, which had an average score of about 11. As a result, scores of 60 or more for the ''Barriers and Access to Care'' section were routinely obtained.

Current NFA Disparity Factors—Frequency of use by applicants. A similar analysis of the ''Health Disparity Factors'' selected by the same group of applicants showed that 8 indicators were selected by 50% or more of the applicants, and another 7 indicators were selected by one-third or more applicants. Twelve indicators were selected by 25% or fewer of the applicants. Ninety-five percent of the time a selected indicator received 3 points; only 5% of the time did an applicant receive 0 rather than 3 points for a disparity indicator supplied. Therefore, typically, at least 27 points were received for the ''Health Disparities Factors'' section. Combining at least 60 points for the ''Barriers and Access to Care'' section access barriers and 27 points for the ''Health Disparities Factors'' section, a typical application would get 87 points, easily exceeding the threshold of 70.

Distribution of All U.S. Counties on Current NFA Barrier Score Levels. To arrive at an understanding of why the scores for access barriers ran so high for most applications, an analysis of the scores that would be achieved by all 3,141 U.S. counties or county-equivalents was conducted. This analysis showed that, given the existing scales:

• On *Percent Below 200% of Poverty*, 665 of 3141 counties receive 14 points, another 993 receive 12 points, and 946 receive 10 points. The average county score is 11 points.

• On *Life Expectancy*, only 17 counties receive 14 points, but 601 counties receive 12 points, and 2,140 receive 10 points. The average county score is 10.1 points.

• On *Unemployment Rate*, the counties are distributed more evenly along the scoring scale, but only 2 counties receive zero points, and the average county score is 9.5 points.

• On *Percent Uninsured*, 1,609 counties receive 10 points, while 1,327 receive 8 points. The average county score is 9 points.

• By contrast, *Travel Time/Distance* shows better distinctions among counties using its existing scale; while 1,527 counties receive zero points, 950 receive 6 points, 294 receive 8 points, 112 receive 10 points, 52 receive 12 points and 51 receive 14 points. The average score is 3.5. HRSA is requesting feedback as to whether the scale should be adjusted to increase the numbers of counties getting 10, 12 or 14 points?

• In the case of *Language other than English,* the current scale seems to err in the direction of overly minimizing the points received: 2,410 counties receive zero points, and the average county score is only 1.8 points.

• On *Shortage of Primary Care Physicians,* 2,565 counties receive no points while 576 receive 14 points. This means that about one-sixth of counties are getting the maximum points, because they are wholly designated as HPSAs. This does not provide any flexibility in terms of the rest of the counties, some of which may be closer to eligibility for HPSA designation than others, while others contain part-county HPSAs.

Recommendations for Revising NFA Criteria/Worksheet. Based on the analysis described above, feedback from communities, applicants and several focus group sessions, HRSA is proposing the following changes to the NFA criteria and process:

• Require that three (3) major access barriers be measured for all applicants. These three would be (a) percent of the population with incomes below 200 percent of the poverty level, (b) percent of population uninsured, and (c) shortage of primary care physicians, the three barriers that are most frequently selected by applicants.

• Use the population-to-primary care physician ratio for the applicant's service area or target population as the measure of shortage of primary care physicians, rather than a simple yes/no response based on presence or absence of a HPSA designation, with a scale of the type used for the other access indicators.

• Allow the applicant to select two additional access barriers from the following five (5): Unemployment Rate of Population, Percent Linguistically Isolated Population (replacing language other than English), Standardized Mortality Rate for Population (replacing Life Expectancy Rate), Travel Time/Distance to Nearest Provider accepting Medicaid and/or Uninsured Patients, and (for Homeless or Public Housing applicants only) Waiting time for Public Housing.

• Choose the scale for each of the access indicators based on comparison to the national county distribution of that indicator. (The scales proposed to be used are displayed below.) No points would be awarded for a barrier value better than the national county median.

• Require that 5 ''core'' disparity factors closely related to health center primary care activities be measured for all applicants. The core indicators proposed are: asthma rate, diabetes rate, and cardiovascular disease rate among the population; one birth outcome measure (infant mortality rate or low live birthweight rate), and one mental health measure (depression rate or suicide rate) among population. [Of these factors, all but one (depression rate) were in the group of current indicators selected at least 33% of the time.]

• Allow 2 points for each core disparity factor on which the community value exceeds the national benchmark for that factor, which would be provided in HRSA's application guidance (rather than by the applicant). Allow an additional point if a higher ''severe'' benchmark, also specified in the guidance, is also exceeded. (Benchmarks proposed are appended below.)

• Have the applicant select 5 additional disparity factors from a list of 7 factors previously used that are closely related to health center primary care activities. The factors proposed are: immunization rate, hypertension rate, rate of respiratory infection, obesity, teenage pregnancy, substance abuse, and percent elderly population. Alternatively, the applicant may select 4 of these plus an ''other'' indicator specified by the applicant.

• Allow 2 points for each selected measure on which the community value exceeds the national benchmark. (Benchmarks proposed are appended below.) If ''other'' is selected, the applicant would need to both define the measure and suggest a benchmark for it as well. If the measure and the benchmark are accepted (or if the

measure is accepted but the benchmark is redefined), 2 points would be allowed if the benchmark is exceeded.

- Maximum possible total points for access barriers here is 75; and for disparities is 25 points, totaling 100 possible total points for NFA.
- A threshold of 50 points on this revised index is under consideration. Only those applicants with a NFA score of 50 or more would have their application reviewed by the ORC. HRSA is considering whether this threshold should be changed annually to maintain a certain ratio of number of applications reviewed to number of awards available.
- The NFA scores achieved could be factored into the application review process.

Relative Importance of Need as an Application Review Factor

The evaluation team also recommended that the relative need score from the NFA worksheet should be the basis for 20 percent of total application score, replacing the previous 10% for ''description of service area/community and target population.'' To accommodate this change, the evaluation team suggested reducing the proportion of the total application score now assigned to ''Governance'' from 10% to 5%, and reducing the proportion of total score assigned to ''Service Delivery Strategy and Model'' from 20% to 15%. However, HRSA has not taken a position on what new relative weighting might be most appropriate. Instead, by this notice, we are requesting public comments on this issue. Specifically, how should Need considerations be weighted in the application review process? What is the relative importance of Need versus such other factors as applicant Readiness to operate a health center, understanding of and connections to the local health care Environment, service delivery Strategy for addressing the needs of the community, plan for provision of specific required health Services, Organizational capabilities and expertise, Budget plan, and Governance? Rather than providing specific suggested percentages for weighting all these different factors, commenters are encouraged to isolate how Need should be weighted relative to all other factors, and whether this should be done by applying that weight to an objective index of relative community need such as that proposed above, or in some other manner.

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Proposed New Scales for NFA Access Barrier Indicators

1A. Core Barriers

For all 3 of the following indicators, give the most current value for an area which most closely approximates the proposed service area or target population.
For each indicator, give data source and year, and identify the reference area [by zip code(s), census tracts, or county] and/or population group used.
Scores will be assigned using the scales shown.

a. Population to Primary Care Physician Ratio

Ratio Range	Score
<1900	0
1900-1949	1
1950-1999	2
2000-2049	3
2050-2099	4
2100-2199	5
2200-2299	6
2300-2399	7
2400-2499	8
2500-2799	9
2800-3099	10
3100-3399	11
3400-4199	12
4200-4999	13
5000-5799	14
5800 or >5800	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____

Area Used:

b. Percent of Population Below 200 percent of poverty

Percent Range	Score
<40.5	0
40.5-43.5	3
43.5-46.5	6
46.5-50.0	9
50.0-55.0	12
>55.0	15

Value: _____
Data Source: _____

Data Year: _____
Area Used: _____ _____

c. Percent of Population Under Age 65 Uninsured

Percent Range	Score
<15.1	0
15.1-16.6	3
16.6-18.2	6
18.2-20.1	9
20.1-22.1	12
>22.1	15

Value: _____
Data Source: _____
Data Year: _____

Area Used:

Proposed New Scales for NFA Access Barrier Indicators, continued

1B. Other barriers

Applicants for funding under Section 330 (e) or (g): For **2 of the first 4 barriers listed below**, give the most current available value for an area/population group which most closely approximates the proposed service area and/or target population
Applicants for funding under Section 330 (h) or (i): For **2 of the 5 barriers listed below**, give the most current value for an area/population group which most closely approximates the proposed service area and/or target population.
For each indicator, give data source and year, and identify the reference area/population group used [by zip code(s), census tracts, or county].
Scores will be assigned using the scales shown.

d. Distance (miles) to nearest provider accepting New Medicaid patients and/or uninsured patients

Mileage Range	Score
<12	0
12-14	3
14-17	6
17-21	9
21-28	12
>28	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____
Area Used: _____

e. Percent of Population Linguistically Isolated

Percentage Range	Score
<0.3	0
0.3-0.5	3
0.5-0.7	6
0.7-1.2	9
1.2-2.8	12
>2.8	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____
Area Used: _____

f. Standardized Mortality Ratio

Ratio Range	Score
>74.3	0
73.8-74.3	3
73.2-73.8	6
72.5-73.2	9
71.4-72.5	12
<71.4	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____
Area Used: _____

g. Unemployment Rate

Rate Range	Score
<5.0	0
5.0-5.7	3
5.7-6.6	6
6.6-7.5	9
7.5-9.3	12
>9.3	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____
Area Used: _____

For 330(h) and (i) Applicants only:

h. Length of waiting time for public housing

Waiting Time Range	Score
< 90 days	0
3-6 months	3
6-12 months	6
12-18 months	9
18-24 months	12
> 24 months	15

Value: _____ _____
Data Source: _____ _____
Data Year: _____ _____
Area Used: _____ _____

Proposed Benchmarks for Disparities Indicators

2. Disparities

For ten disparity indicators, indicate the most current available value for an area or population group that most closely approximates the community, service area or target population proposed to be served. These will be compared with the benchmarks shown.

Include the data source, data year, and reference area or population group used.

All applicants must respond to the core disparities (1-5 below; two options each for 4 and 5.) 2 points are awarded if the area's value exceeds the benchmark X, and an additional point if the area's value exceeds the more severe threshold Y.

Choose any 5 of disparities 6-13; for each of these, 2 points are awarded if the benchmark X is exceeded.

	Benchmark (X)	Severe Threshold (Y)	Service Area Value	Source	Area	Year
Core Disparities (possible 2 or 3 Points each)						
1. Asthma	Prevalence: 7.6% of the population	Prevalence: 8.3% of the population				
2. Diabetes	26 diabetic deaths per 100,000 residents	35 diabetic deaths per 100,000 residents				
3. Cardiovascular	205 ischemic deaths per 100,000 residents	260 ischemic deaths per 100,000 residents				
4. Birth Outcomes						
a. Infant Mortality Rate (IMR) or	8 infant deaths per thousand live births	10 infant deaths per thousand live births				
b. Low Live Birthweight Rate (LBW)	7% of births are low birthweight births	8% of births are low birthweight births				
5. Mental Health						
a. Suicide Rate, or	12 per 100,000 residents	16 per 100,000 residents				
b. Depression Rate	TBD	TBD				
Other Disparities (possible 2 Points each)						
6. Teenage pregnancy rate	Pregnancies among 1.7% or more of females age 13-17					
7. Substance Abuse	TBD					
8. Immunization Rate	Less than 80% of children aged 19 to 35 months have received 4:3:1 vaccination series (4 DPT,3 polio, 1measles)					
9. Hypertension rate	25% of population have been told they have high blood pressure					
10. Rate of respiratory infection	More than 1.0 deaths per 10,000 due to pneumonia over 3 years					
11. Obesity	23% of adults classified as obese					
12. Percent of Population Aged 65+	15% of population					
13. Other*						

* Any "Other" indicator must be health related and specific to the target population to be served (as outlined in the application). Applicant must specify a suggested benchmark and provide the source of that benchmark

DATES: Please send comments no later than COB March 7, 2005. The comments should be addressed to Dr. Sam Shekar, Associate Administrator for Primary Health Care, Health Resources and Services Administration, Room 17–99,

5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Lynn Spector, Division of Health Center Development, Bureau of Primary Health Care, HRSA. Ms. Spector may be contacted by e-mail at *lspector@hrsa.gov* or via telephone at (301) 594–4300.

Dated: February 1, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–2215 Filed 2–1–05; 4:24 pm]

BILLING CODE 4165–15–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Physical Activity and Its Components In Relation To Plasma Inflammatory Markers of Cancer Risks Among Chinese Adults

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Physical Activity And Its Components In Relation To Plasma Inflammatory Markers Of Cancer Risks Among Chinese Adults.

Type of Information Collection Request: NEW.

Need and Use of Information Collection: The specific objectives of the current study are to: (1) Develop a comprehensive physical activity questionnaire that includes standardized questions about all types of physical activity (*e.g.*, recreational, household, occupational, and transportation), and all parameters of physical activity (*e.g.*, frequency, intensity; and duration in hours per week; (2) to assess the validity and reliability of this comprehensive physical activity questionnaire and the currently used baseline physical activity questionnaire in two existing study cohorts using objective measures of physical activity/physical fitness (activity monitors and step test), and; (3) to evaluate whether types and parameters of physical activity are associated with circulating levels of specific inflammatory markers that have been linked to cancer risk, independent of body mass and other potentially confounding variables. The specific markers are C-reactive protein (CRP), interleukin 6 (IL–6), and soluble tumor necrosis factor alpha (TNF-'').

The findings of this study will contribute to research in several important ways. They will allow the collection of objective physical activity measurements using activity monitors within a population with a wide range of between-person variation in physical activity; add to our understanding of the relationship of individual types of physical activity (*e.g.*, recreational, household, occupational, and transportation), and parameters of physical activity (*e.g.*, frequency, intensity, and duration in hours per week) to cancer outcomes; allow the use of physical activity information together with detailed, prospectively collected information regarding other lifestyle factors, such as diet and body mass, factors that are highly correlated with physical activity and also represent strong independent determinants of inflammatory mediator production, and; should the anticipated associations be found, the current study will likely stimulate future studies aimed at independently and jointly evaluating physical activity and chronic low-grade systemic inflammation in relation to cancer of several sites.

Frequency of Response: Once a month during a twelve-month period.

Affected Public: Approximately 600 men and women from a current cohort study among 75,000 women and 73,000 men and residing in Shanghai, China who agree to participate in this study.

Type of Respondents: Adult men and women aged 40 to 70 years old who are residents of Shanghai, China and current participants in another ongoing study. The annual reporting burden is as follows:

Estimated Number of Respondents: 600.

Estimates of Respondent Hour Burden and Annualized Cost to Respondents:

Type of respondents	Survey instruments per respondents	Number of participants	Frequency of response	Average burden hours per response	Total annual hour burden
Adults (40–70 yrs old)	Physical Activity Questionnaire	600	2	0.5	600
	7-Day Physical Activity Record	600	4	1.4	3360
	1-Week Physical Activity Recall	600	12	0.25	1800
TOTAL		600			5,760

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Michael F. Leitzmann, M.D., Dr. P.H., Nutritional Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS, 6120 Executive Blvd., EPS–MSC 7232, Bethesda, MD, 20892, U.S.A. or call non-toll-free number 301–402–3491 or E-mail your request, including your address to: *leitzmann@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 25, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 05–2127 Filed 2–3–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Announcement of Plans for Future Evaluation of Di(2-ethylhexyl)phthalate; Request for Public Comments on this Chemical; and Solicitation for the Nomination of Scientists Qualified to Serve on an Expert Panel

AGENCY: National Institute for Environmental Health Sciences (NIEHS); National Institutes of Health (NIH), Department of Health and Human Services (HHS).

ACTION: Notice of expert panel evaluation of the reproductive and developmental toxicities of di(2-ethylhexyl)phthalate.

SUMMARY: The CERHR plans to convene an expert panel to evaluate the scientific evidence regarding the potential reproductive and/or developmental toxicity associated with exposure to di(2-ethylhexyl)phthalate (DEHP). The expert panel will consist of approximately 8–12 scientists selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other relevant areas of science. The CERHR invites the submission of public comments on DEHP and the nomination of scientists to serve on the expert panel for its evaluation (*see* **SUPPLEMENTARY INFORMATION** below). This meeting is tentatively scheduled for fall 2005, although the exact date and location are not yet established. As plans are finalized, they will be announced in the **Federal Register** and posted on the CERHR Web site (*http://cerhr.niehs.nih.gov*). CERHR expert panel meetings are open to the public with time scheduled for oral public comment.

DATES: Information and comments received by March 21, 2005, will be made available to the CERHR staff and the expert panel for consideration in the evaluation and posted on the CERHR Web site. Nominations of scientists received by March 21, 2005, will be considered for this panel and for inclusion in the CERHR Expert Registry.

ADDRESSES: Information and comments should be sent to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC–32, Research Triangle Park, NC 27709 (mail), (919) 316–4511 (fax), or *shelby@niehs.nih.gov* (e-mail). Courier address: CERHR, 79 T.W. Alexander Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. Michael D. Shelby, CERHR Director, (919) 541–3455, *shelby@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

DEHP is a high production chemical used as a plasticizer of polyvinyl chloride in the manufacturer of a wide variety of consumer products, such as building products, car products, clothing, food packaging, children's products (but not in toys intended for mouthing) and in polyvinyl chloride medical devices. In 1999–2000, a NTP–CERHR expert panel evaluated DEHP and six other phthalates for reproductive and developmental toxicities. Since release of the NTP-CERHR expert panel report on DEHP in 2000, approximately 70 papers relevant to human exposure and reproductive and/or developmental toxicity of DEHP have been published. Because this is a chemical with wide human exposure and public and government interest, CERHR plans to convene an expert panel to conduct an updated evaluation of the potential reproductive and developmental toxicities of DEHP.

Request for Comments

The CERHR invites the public and other interested parties to submit information and comments on DEHP including toxicology information from completed and ongoing studies, information on planned studies, and information about current production levels, human exposure, use patterns, and environmental occurrence.

Request for the Nomination of Scientist for the Expert Panel

The CERHR invites nominations of qualified scientists to serve on the expert panel. Panelists are primarily drawn from the CERHR Expert Registry and/or the nomination of other scientists who meet the criteria for listing in that registry which include: formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, membership in relevant professional societies, and certification by an appropriate scientific board or other entities. Expert panel members are required to sign conflict of interest forms in accordance with Federal Advisory Committee Act Guidelines (5 U.S.C. Appendix 2).

All panel members serve as individual experts and not as representatives of their employers or other organizations. Scientists on the expert panel will be selected to represent a wide range of expertise including, but not limited to, developmental toxicology, reproductive toxicology, epidemiology, general toxicology, pharmacokinetics, exposure assessment, and biostatistics. Nominations should include contact information and a current curriculum vitae (if possible) and be forwarded to the CERHR at the address given above.

Background Information on the CERHR

The NTP established the CERHR in June 1998 (**Federal Register**, December 14, 1998: Volume 63, Number 239, page 68782). The CERHR is a publicly accessible resource for information about adverse reproductive and developmental health effects associated with environmental exposures. Expert panels conduct scientific evaluations of agents selected by the CERHR in public forums.

Information about CERHR and its process for nominating agents for review or scientists for its expert registry can be obtained from its Web site (*http://cerhr.niehs.nih.gov*) or by contacting Dr. Shelby (contact information provided above). The CERHR selects chemicals for evaluation based upon several factors, including production volume, extent of human exposure, public concern, and extent of the database on reproductive or developmental toxicity studies.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process was published in the **Federal Register** (July 16, 2001: Volume 66, Number 136, pages 37047–37048) and is available on the CERHR Web site under ''About CERHR'' or in printed copy from the CERHR.

Dated: January 27, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 05–2125 Filed 2–3–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92–463, notice is hereby given of the sixth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to 5:30 p.m. on February 28, 2005 and 8:30 a.m. to 5 p.m. on March 1, 2005 at the Bethesda North Marriott Hotel, 5701 Marinelli Road, North Bethesda, Maryland. The meeting will be open to the public with attendance limited to space available. The meeting will be webcast.

The meeting is expected to include presentations and deliberations on several topics, including the following: a revised draft report with recommendations about coverage and reimbursement for genetic technologies and services; current and proposed efforts to understand gene-environment interactions through large population studies; the Committee's efforts to explore stakeholder perspectives on the need for Federal legislation to prevent genetic discrimination in health insurance and employment; the recommendations of the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children regarding the provision of screening, counseling and health care services for newborns and children having or at risk for heritable disorders; and efforts to improve the quality of laboratory testing for rare diseases. Time will be provided each day for public comments.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. The draft meting agenda and other information about SACGHS, including information about access to the webcast, will be available at the following Web site: *http://www.od.nih.gov/oba/sacghs.htm.*

The Committee would welcome hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or e-mail at *sc112@nih.gov.* The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Dated: January 27, 2005.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–2128 Filed 2–3–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Disorders; 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for type 1 diabetes. The outcome of the evaluation will be a decision whether NIDDK should support the request and make available contract resources for development of the potential therapeutic to improve the treatment or prevent the development of type 1 diabetes and its complications. The reserach proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Type 1 Diabetes—Rapid Access to Intervention Development Special Emphasis Panel, National Institute of Diabetes and Digestive and Kidney Diseases.

Date: February 9, 2005.

Time: 10 a.m.–2 p.m.

Agenda: To evaluate requests for preclinical development resources for potential new therapeutics for type 1 diabetes and its complications.

Place: 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone conference call.)

Contact Person: Dr. Myrlene Staten, Senior Advisor, Diabetes Translation Research, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK, NIH, 6707 Democracy Boulevard, Bethesda, MD 20892–5460. (301) 402–7886.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research, 93.848, Digestive Diseases and Nutrition Research; 98.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS.)

Dated: January 26, 2005

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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.

[FR Doc. 05–2131 Filed 2–3–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the third meeting of the Commission on Systemic Interoperability.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The mission of the Commission on Systemic Interoperability is to submit a report to the Secretary of Health and Human Services and to Congress on a comprehensive strategy for the adoption and implementation of health care information technology standards that includes a timeline and prioritization for such adoption and implementation. In developing that strategy, the Commission will consider: (1) The costs and benefits of the standards, both financial impact and quality improvement; (2) the current demand on industry resources to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other electronic standards, including HIPAA standards; and (3) the most cost-effective and efficient means for industry to implement the standards.

Name of Committee: Commission on Systemic Interoperability.

Date: March 15, 2005.
Time: 8 a.m. to 4 p.m.
Agenda: Healthcare Information Technology Standards.
Place: Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, Washington, DC 20201.
Contact Person: Ms. Dana Haza, Director, Commission on Systemic Interoperability, National Library of Medicine, National Institutes of Health, Building 38, Room 2N21, Bethesda, MD 20894. (301) 594–7520.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

In the interest of security, HHS has procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. at the security desk upon entering the building.

Dated: January 28, 2005.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–2130 Filed 2–3–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of 3-deazaneplanocin A and Cyclopentenyl Cytosine for the Development of the Topical Treatment of Basal Cell Carcinoma and Resistant Herpes Simplex Virus Infections

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a an exclusive license to practice the invention embodied in:

(1) U.S. Patent No. 4,968,690, issued Nov. 6, 1990, entitled ''3-DEAZANEPLANOCIN A AND METHOD OF PREPARATION'' (E–493–1985/0–US–02) (Inventors: Victor E. Marquez, John S. Driscoll, Mu–III Lim, Christopher K Tseng, Alberto Haces and Robert Glazer) (NCI), a continuation of prior application 867,583, filed May 27, 1986, now abandoned.

(2) U.S. Patent No. 4,975,434, issued Dec. 4, 1990, entitled ''ANTIVIRAL AND ANTICANCER CYCLOPENTENYL CYTOSINE'' (E–493–1985/1–US–01) (Inventors: Victor E. Marquez, John S. Driscoll, Mu–III Lim, Christopher K Tseng, Alberto Haces and Robert Glazer) (NCI), a continuation of prior application 867,583, filed May 27, 1986, now abandoned to GRX Pharmaceuticals (hereafter GRX), having a place of business in Marlboro, New Jersey. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before April 5, 2005, will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Sally Hu, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; e-mail: *hus@od.nih.gov*; telephone: (301) 435–5606; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: The technology described in E–493–1985/0–US–02 relates to antiviral and cancer chemotherapy and, more particularly, to the compound 3-deazaneplanocin A and related compounds and a method of preparation thereof, as well as the methods of preparation of a great variety of unsaturated (cyclopentenyl) carbocyclic nucleosides.

The technology described in E–493–1985/1–US–01 relates to antiviral and cancer chemotherapy and, more particularly, to cyclopentenyl pyrimidines which can be used for antiviral and cancer chemotherapy, as well as to methods of preparation of these compounds.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to the development of the topical treatment of basal cell carcinoma and resistant herpes simplex virus infections.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 21, 2005.

Mark L. Rohrbaugh,

Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–2126 Filed 2–3–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Construction and Operation of the National Biodefense Analysis and Countermeasures Center (NBACC) Facility by the Department of Homeland Security at Fort Detrick, Maryland: Record of Decision

AGENCY: Science and Technology Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: In keeping with the purposes of the National Environmental Policy Act (NEPA), the Department of Homeland Security (DHS), in cooperation with the United States Army Garrison, Fort Detrick, decided on January 26, 2005, after completion of the Final Environmental Impact Statement (FEIS) and a thorough consideration of public comments, to implement the Preferred Alternative in the FEIS. This action involves the construction and operation of the National Biodefense Analysis and Countermeasures Center Facility by DHS on a site adjacent to existing U.S. Army Medical Research Institute of Infectious Diseases facilities at Fort Detrick, Maryland. The notice of availability of the Draft Environmental Impact Statement is at 69 FR 56075 and the notice of intent to prepare an Environmental Impact Statement is at 69 FR 31830.

ADDRESSES: Copies of the Final EIS and this Record of Decision may be obtained by calling or mailing a request to: Dr. Kevin Anderson, Department of Homeland Security, 7435 New Technology Way, Suite A, Frederick, Maryland, 21703, by telephone (301) 846–2156, fax (301) 682–3662 or e-mail *kevin.anderson@dhs.gov.* The Final EIS and this Record of Decision are available at *http://www.detrick.army.mil/.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the Final EIS or this Record of Decision can be submitted by calling or mailing them to Dr. Kevin Anderson at the above phone number or address.

SUPPLEMENTARY INFORMATION:

Record of Decision

Background

The Department of Homeland Security, DHS, and the United States Army Garrison, Fort Detrick (Cooperating Agency), have decided, after completion of the Final Environmental Impact Statement (FEIS) and a thorough consideration of public comments, to implement Alternative I (the Proposed Action), which was identified as the Preferred Alternative in the FEIS. This action involves the construction and operation of the National Biodefense Analysis and Countermeasures Center (NBACC) Facility by DHS on a site adjacent to existing U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) facilities at Fort Detrick, Maryland.

The Biological Threat Characterization Center (BTCC) and the National Bioforensics Analysis Center (NBFAC), both components of DHS, will occupy the NBACC Facility, which will contain Biosafety Level (BSL) 2, 3, and 4 laboratory and animal research facilities for conducting studies with disease-causing microbes which spread through the air or have an unknown cause. NBACC's biodefense mission is different from, but complementary to, those of USAMRIID and the National Institutes of Health (NIH) Integrated Research Facility (IRF), currently under construction at an adjoining site.

Alternatives Considered

Two alternatives were identified and evaluated in detail in the FEIS. They are Alternative I, the Proposed Action, and, Alternative II, No Action. Implementation of the Proposed Action may result in negligible to minor adverse impacts to the physical, biological, and socioeconomic environment. In instances where unavoidable minor adverse environmental impacts are anticipated, mitigation measures to lessen the negative effects have been identified. Under the No-Action Alternative, DHS would not build the NBACC Facility, and the potential negligible to minor adverse impacts associated with the Proposed Action would not occur. Although the No-Action Alternative would be environmentally preferable, its implementation would not address the needs of DHS for BSL 3, and 4 laboratory and animal research facilities.

Three additional alternatives for construction and operation of the NBACC Facility by DHS were identified but rejected as unreasonable and, therefore, were not evaluated in detail in the FEIS. These are: (1) Construction and Operation of the NBACC Facility by DHS at Another Location within Fort Detrick (Alternative III); (2) Construction and Operation of the NBACC Facility by DHS on an Existing Government-owned Property Outside Fort Detrick (Alternative IV); and (3) Construction and Operation of the NBACC Facility by DHS on a Currently Privately-owned Property Outside Fort Detrick (Alternative V). The rejected alternatives, along with the reasons for their elimination, are described below.

Factors Involved in the Decision

It was determined that the Proposed Action best satisfies DHS's needs for BSL–3 and BSL–4 laboratory and animal facilities for BTCC research and for support of operations in NBFAC. It is in accord with Fort Detrick's Installation Master Plan and conforms to USAG's planning and environmental policies. The construction and operational phases of the project will have no significant, non-mitigable, adverse environmental impacts and will result in negligible to minor risks to health and safety of the public and the workforce.

The potential adverse impacts were deemed to be mitigable through compliance with existing regulatory requirements, application of Best Management Practices (BMPs), and adherence to construction contract requirements. DHS will incorporate operational and safety safeguards in the facility to protect laboratory workers and local residents from possible harmful health and safety effects related to the operation of the facility. Operation of the NBACC Facility will not adversely impact City of Frederick residents.

None of the other alternatives examined in the EIS, including the No-Action Alternative, would be better suited to the needs of DHS. Moreover, the Proposed Action allows DHS to address a critical national shortage in BSL–4 facilities and fits the critical characteristics for location in or near the National Capital area and co-location with existing BSL–3 and BSL–4 laboratories and associated existing specialized supporting infrastructure for biocontainment facility operations, including response and security services.

Although options to locate the NBACC Facility on an alternate site at Fort Detrick (Alternative III) were also considered during the scoping process for the EIS, this is not consistent with Fort Detrick land use planning. Moreover, in comparison to the Proposed Action, it would be more distant from the existing USAMRIID facilities and the NIH IRF now under construction, and therefore, less favorable for utilization of existing infrastructure and for synergy among personnel of the three agencies.

Alternatives that would involve locating the NBACC Facility on a site outside of Fort Detrick, either on existing government-owned property (Alternative IV) or on currently privately-owned property (Alternative V) also were eliminated from detailed evaluation in the EIS during the scoping process. Those alternatives could require costly land acquisition and infrastructure development that could delay completion of the NBACC Facility by several years. Furthermore, it would be contrary to congressional intent for the building to be built outside Fort Detrick.

Practicable Means To Avoid or Minimize Potential Environmental Harm from the Selected Alternative

All practicable means to avoid or minimize adverse environmental effects from the selected action have been identified and incorporated into the selected action. Pollution prevention measures incorporated in the selected action include:

- Reducing construction waste by recycling materials wherever possible;
- Applying BMPs during construction to minimize soil erosion and potential airborne particulate matter,
- Including new state-of-the-art energy efficient equipment in the facility to reduce the energy demand on Fort Detrick electrical systems;
- Rendering all contaminated or potentially contaminated medical waste noninfectious by a combination of chemical and physical (autoclaving) methods before disposal or transport off-site;
- Sterilizing laboratory wastewater within the laboratories and, secondarily, within the facility itself through chemical disinfection or steam sterilization methods before discharging wastewater into the Fort Detrick sanitary sewer system;
- Employing High Efficiency Particulate Air filters to capture small particles in laboratory exhaust air before venting the air to the outside; and
- Requiring that NBACC Facility activities comply with the DHS waste management policies, which emphasize source segregation, inactivation, source reduction, reuse, and recycling.

Mitigation Measures, Monitoring and Enforcement

During the preparation of the FEIS several potential adverse environmental

impacts associated with implementation of the selected action were identified. These included land use (land disturbance), construction noise, transportation (traffic and parking), geology (potential sinkholes), surface water resources (sedimentation, stormwater management, water supply), plant and animal ecology (displacement of deer and/or bird species), air quality (fugitive dust during construction, increased pollutant emissions during operation, increased vehicular emissions), and pollution prevention/waste management (construction wastes and handling and disposal of waste generated during operation). These potential adverse impacts were deemed to be negligible to minor, and mitigable through compliance with existing regulatory requirements, application of BMPs, and adherence to construction contract requirements.

In addition, possible adverse health and safety impacts on laboratory workers in the NBACC Facility and on nearby residents during the operational phase of the project were evaluated. The risks were deemed to be negligible to minor, and mitigable through adherence to guidelines outlined in *Biosafety in Microbiological and Biomedical Laboratories,* a joint publication of the Centers for Disease Control and the NIH, as well as other standards for safe operational practices.

Since potential adverse impacts would be mitigated by compliance with existing regulatory requirements, application of BMPs, and adherence to construction contract requirements, existing regulatory reporting requirements and contract administration procedures will serve in lieu of a formal Monitoring and Enforcement Program.

Conclusion

Based upon review and careful consideration of the impacts identified in the FEIS, results of various environmental and hazard assessment studies conducted in conjunction with the DEIS; public comments received throughout the National Environmental Policy Act process, including comments on the DEIS and comments received during the required 30-day waiting period for the FEIS, as well as other relevant factors, such as congressional intent, DHS and USAG, Fort Detrick, have decided to implement Alternative I, the Proposed Action, Construction and Operation of the NBACC Facility by DHS on a Site Adjacent to Existing USAMRIID Facilities at Fort Detrick, Maryland.

Dated: January 27, 2005.

Maureen I. McCarthy,

Director, Research and Development, Science and Technology Directorate, Department of Homeland Security.

[FR Doc. 05–2092 Filed 2–3–05; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Privacy Act of 1974; Systems of Records

AGENCY: Department of Homeland Security.

ACTION: Notice of computer matching programs.

SUMMARY: In accordance with the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988, the Department of Homeland Security is giving notice of computer matching programs that its component agency, United States Citizenship and Immigration Services, will conduct with five state agencies.

DATES: Matching activities under the new agreements will be effective March 7, 2005, or 40 days after a report concerning the computer matching programs has been transmitted by the Department of Homeland Security to the Office of Management and Budget and transmitted to Congress with a copy of the agreements, whichever is later.

FOR FURTHER INFORMATION CONTACT: Nuala O'Connor Kelly, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528 by telephone (202) 772–9848 or facsimile (202) 772–5036.

SUPPLEMENTARY INFORMATION:

A. Background

The Privacy Act, as amended by the Computer Matching and Privacy Protection Act of 1988, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. The Privacy Act requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement(s) by the Data Integrity Board of the participating Federal agencies;

(3) Publish notice of the computer matching program(s) in the **Federal Register**;

(4) Furnish detailed reports about the matching programs to Congress and to the Office of Management and Budget (OMB);

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating, or denying an individual's benefits of payments.

The Department of Homeland Security (DHS) has taken action to ensure that these requirements are met by the matching agreements at issue in this notice.

B. Legal Authority

The legal authority for the relevant disclosures in these matching operations is contained in Section 21 of the Immigration Reform and Control Act (IRCA) of 1986 (Pub. L. 99–603), as amended by the Personal Responsibility and Work Opportunity Reconciliation Act (PRWPRA) (Pub. L. 104–193). This statute requires United States Citizenship and Immigration Services (USCIS) to establish a system for the verification of immigration status of alien applicants for, or recipients of, certain types of benefits, and to make this system available to state agencies which administer such benefits.

C. The Matching Agreements

The matching agreements at issue in this notice involve information obtained from USCIS, which is the source agency. The information will be used by the recipient agencies to confirm the immigration status of alien applicants for, or recipients of, Federal benefits assistance under the ''Systematic Alien Verification for Entitlements'' (SAVE) Program. Specifically, the matching activities will permit the following eligibility determinations:

(1) The New York Department of Labor, New Jersey Department of Labor and Workforce Development, Massachusetts Division of Employment and Training, and the Texas Workforce Commission will be able to determine eligibility status for unemployment compensation;

(2) The California Department of Social Services will be able to determine eligibility status for the Temporary Assistance for Needy Families (TANF) Program, and the Food Stamps Program;

(3) The California State Department of Health Services will be able to determine eligibility status for the Medicaid Program.

Employing user identification codes and passwords, authorized persons from the state agencies listed above may electronically access the database of the

CIS system of records entitled ''Verification Information System, Justice/INS 035,'' last published in the **Federal Register** on October 17, 2002. This system of records is used to provide immigration status information to Federal, State, and local government agencies for immigrants and naturalized U.S. citizens applying for public benefits. By accessing the USCIS database, these state agencies may obtain an alien registration number for the potential applicant or beneficiary for public benefits. Where the alien registration number is located, the state agency will receive electronically from the USCIS database the following data upon which to determine eligibility: The alien registration number, last name, first name, date of birth, country of birth, social security number (if available), date of entry, immigration status data, and employment eligibility data. If the state agency determines that an alien is not entitled to public benefits, in accordance with 5 U.S.C. 552a(p), the state agency will provide the alien applicant with 30 days notice and an opportunity to contest any adverse finding before final action is taken against that alien because of ineligibility as established through the computer match.

DHS has approved agreements to permit these computer matching programs for an 18-month period. The matching program may be extended for an additional 12 months thereafter, if certain conditions are met. Matching activities under the new agreements will be effective 30 days after publication of this computer matching notice in the **Federal Register**, or 40 days after a report concerning the computer matching programs has been transmitted to the Office of Management and Budget (OMB) and transmitted to Congress with a copy of the agreements, whichever is later.

In accordance with 5 U.S.C 552a(o)(A) and (r), the required report has been provided to the Office of Management and Budget, and to the Congress together with a copy of the agreements.

Dated: January 30, 2005.

Nuala O'Connor Kelly,

Chief Privacy Officer.

[FR Doc. 05–2168 Filed 2–3–05; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1573–DR]

Indiana; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Indiana (FEMA–1573–DR), dated January 21, 2005, and related determinations.

EFFECTIVE DATE: January 27, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Indiana is hereby amended to include Public Assistance in the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of January 21, 2005:

Adams and Wayne Counties for Public Assistance.

Blackford, Boone, Clinton, Delaware, Fountain, Grant, Henry, Howard, Jay, Madison, Montgomery, Randolph, Tippecanoe, Tipton, and Warren Counties for Public Assistance (already designated for Individual Assistance.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund 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.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–2113 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3198–EM]

Ohio; Amendment No. 2 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Ohio (FEMA–3198–EM), dated January 11, 2005, and related determinations.

EFFECTIVE DATE: January 26, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Ohio is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of January 11, 2005:

The counties of Erie, Morrow, and Wyandot for emergency protective measures (Category B) under the Public Assistance program for a period of 48 hours.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Assistance.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–2114 Filed 2–3–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4971–N–04]

Notice of Submission of Proposed Information Collection to OMB; Public Housing Assessment System (PHAS): Management Operations Certification

AGENCY: Office of the Chief Information Officer, HUD

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is

soliciting public comments on the subject proposal.

PHAs (or Resident Management Corporations) submit management information for evaluation of all major areas of a participant's management operations. The information is used to assess the management performance of PHAs.

DATES: Comments Due Date: March 7, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2535–0106) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* or Lillian Deitzer at *Lillian_L_Deitzer@HUD.gov* or telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins or Ms. Deitzer and at HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm*

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: PHAS: Management Operations Certification.

OMB Approval Number: 2535–0106.

Form Numbers: HUD–50072.

Description of the Need for the Information and Its Proposed Use: PHAs (or Resident Management Corporations) submit management information for evaluation of all major areas of a participant's management operations. The information is used to assess the management performance of PHAs.

Frequency of Submission: Annually.

	Number of Respondents	Annual Responses	x	Hours per Response	=	Burden Hours
Reporting Burden:	3,174	1		1.14		3,643

Total Estimated Burden Hours: 3,643.

Status: Extension of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 28, 2005.

Wayne Eddins,

Departmental Paperwork Reduction Act Officer, Office of the Chief Information Officer.

[FR Doc. 05–2213 Filed 2–3–05; 8:45 am]

BILLING CODE 4210–72–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4975–N–01]

Notice of Proposed Information Collection: Comment Request

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 5, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410 or *Wayne_Eddins@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anita Hart, Realty Specialist, Office of Regulatory Affairs and Manufactured Housing, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone 708–0502 Ext. 2066 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Interstate Land Sales Full Disclosure Requirements.

OMB Control Number, if applicable: 2502–0243.

Description of the need for the information and proposed use: Developers must register subdivisions of 100 or more non-exempt lots with HUD and provide consumers with a property report prior to sales/lease contract/agreement.

Agency form numbers, if applicable: None.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of respondents is 1,104, the number of responses annually is 26,493, and the number of burden hours is 24,776.

Status of the proposed information collection: Currently approved.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: January 26, 2005.

John C. Weicher,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 05–2214 Filed 2–3–05; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Bon Secour National Wildlife Refuge

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Availability of the Draft Comprehensive Conservation Plan/Environmental Assessment for Bon Secour National Wildlife Refuge in Baldwin County, Alabama.

SUMMARY: The Fish and Wildlife Service announces that a Draft Comprehensive Conservation Plan/Environmental Assessment for Bon Secour National Wildlife Refuge is available for review and comment. The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, requires the Service to develop a comprehensive conservation plan for each national wildlife refuge. The purpose in developing a comprehensive conservation plan is to provide refuge managers with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and Service policies. In addition to outlining broad management direction on conserving wildlife and their habitats, the plan identifies wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation.

Proposed goals for the refuge include:

• Identifying, conserving, managing, enhancing, and restoring populations of native fish and wildlife species representative of coastal Alabama, with special emphasis on migratory birds and threatened and endangered species.

• Identifying, conserving, managing, enhancing, and restoring the natural diversity, abundance, and ecological functions of refuge habitats and associated plant communities, with an emphasis on managing designated critical habitat for threatened and endangered species.

• Identifying and conserving archaeological and natural resources on the refuge and promoting conservation through interagency and private landowner cooperation, partnerships, and land protection programs on the Fort Morgan Peninsula and coastal Alabama.

• Providing the public with quality interpretation, outreach opportunities, environmental education programs, and recreational activities that lead to a greater understanding, enjoyment, and appreciation of fish, wildlife, habitats, and cultural resources of coastal Alabama.

Compatibility determinations for recreational fishing, wildlife observation, photography, hiking, environmental education and interpretation, swimming and beach use, scientific research, dogs on the beach, and bicycling are included in the draft plan.

Proposed Action

The proposed action is to adopt and implement a comprehensive conservation plan for the refuge that best achieves the refuge's purpose, vision, and goals; contributes to the National Wildlife Refuge System mission; addresses the significant issues and relevant mandates; and is consistent with principles of sound fish and wildlife management. The Service analyzed four alternatives for managing the refuge and chose Alternative D as the one to best achieve all of these elements.

Alternatives

Alternative A—Represents the status quo; *e.g.,* no changes from current management of the refuge. Existing refuge management and public outreach practices would be favored under this alternative. All refuge management actions would be directed towards achieving the refuge's primary purposes including: (1) Preserving habitat to ensure the well-being of nationally threatened and endangered species; (2) conserving an undisturbed beach/dune ecosystem which includes a diversity of fish, wildlife, and their habitats; (3) serving as a living laboratory for scientists and students; and (4) providing wildlife-oriented recreation for the public.

Refuge management programs would continue to be developed and implemented with little baseline biological information. Active habitat management would include beach/dune habitat improvement and restoration, protection of nesting sea turtles, and prescribed burning designed to reduce fuel loads. Land would be acquired from willing sellers within the current acquisition boundary totaling approximately 12,570 acres.

Fishing and wildlife observation would continue to be the major focuses of the refuge public use program, with no expansion of current opportunities. Current restrictions or prohibitions would remain. No new trails would be developed, but the refuge staff would continue to maintain the existing trails. Environmental education and interpretation and wildlife photography would be accommodated on a case-by-case basis. Funding to construct a maintenance facility and to rehabilitate existing facilities would be requested.

Alternative B—Expands wildlife and habitat management activities, while maintaining current public use and education. Under this alternative, the emphasis would be to improve refuge resources for wildlife, while still maintaining those public use opportunities which presently exist. Most refuge management actions would be directed toward preserving, enhancing, restoring, and managing the beach/dune habitat for the benefit of the Alabama beach mouse and nesting sea turtles. Prescribed burning would be used to improve habitat for neotropical migratory birds. Other national, regional, and state goals to protect and restore forest, grassland, and scrub/shrub bird populations would be supported secondarily in habitats that are inland from the beach/dune habitat. Baseline data would be collected, standardized surveys implemented, and populations monitored.

Additional staff would include a biological technician and a law enforcement officer to accomplish objectives for establishing baseline data on refuge resources, managing habitats, and protecting biological resources.

Under this alternative the refuge would continue to seek lands from willing sellers within the acquisition boundary. Non-traditional land protection methods would be developed and employed.

Public uses would include wildlife observation and photography, limited interpretation, and fishing. Under this alternative, outreach and environmental education would occur on a sporadic, time-permitting basis. No evaluation of existing uses would occur. Fishing and wildlife observation would continue to be the major focus for the public use program, with no expansion of enhancement of current opportunities. No new trails would be developed, but the refuge staff would continue to maintain the existing trails. All new

funding would support the wildlife and habitat management programs, with annual maintenance funding to support upkeep of existing public use facilities. Partnership opportunities would not be feasible, as full attention would be on managing refuge lands and collecting biological information. This alternative in no way addresses the increase in visitation that has occurred in the past 5 years and that is predicted to continue.

Alternative C—Maintains current wildlife and habitat management activities, while expanding public use and education. This approach would maintain the current wildlife and habitat management activities while allowing for significantly more public recreational uses. Additional staff needed to implement this alternative includes an outdoor recreation planner, a law enforcement officer, and a seasonal maintenance worker. Trails, parking lots, and interpretive signage would be constructed in every refuge unit, along with added environmental education and watchable wildlife programs. Additional staff would be used for developing and presenting both on- and off-site outreach and interpretation programs. A user fee and permit system would be implemented for fishing and beach use. A visitor center and headquarters office would be constructed on the refuge and would include an environmental education classroom and meeting facilities.

Land acquisition within the current acquisition boundary would continue with emphasis on those lands that can provide additional public use opportunities and beach access.

Sporadic beach mouse live-trapping and monitoring of sea turtle nests on refuge beaches would continue. No new surveys on migratory songbirds, breeding songbirds, shorebirds and marshbirds, and wintering shorebirds would occur. Baseline data on herpetofauna would not be collected. Only dune restoration habitat projects would occur. Grassland and scrub/shrub habitat would not be restored and managed and prescribed fire would continue to focus on fuel reduction versus enhancing bird habitats. All new partnerships would be related to visitor services, public outreach, and environmental education.

Alternative D—Expands wildlife and habitat management activities, while optimizing public use and involvement. The Service planning team has identified Alternative D as the preferred alternative. This alternative was developed based on public input and the best judgment of the planning team. The strategies presented in the draft plan were developed as a direct result of the selection of Alternative D.

This alternative would promote a greater understanding and protection of fish, wildlife, and their habitats, and higher quality, balanced recreational opportunities for visitors. Fishing would continue with greater emphasis on the quality of the experience. Education and interpretation would be promoted through regular programs and partnerships with local schools. Wildlife observation and photography opportunities would be expanded, including a kayak trail and observation towers, highlighting refuge management programs and unique wildlife habitats. A user fee and permit would be implemented to facilitate night fishing at Mobile Point. A visitor center and headquarters office would be constructed on the refuge with space for interpretation, environmental education, and staff.

Research studies on the refuge would be fostered and partnerships developed with other agencies and universities to provide needed resources and experiment sites, while meeting the needs of the refuge's wildlife and habitat management programs. Research would also benefit conservation efforts throughout the Central Gulf Coast to preserve, enhance, restore, and manage coastal barrier island habitat. New surveys on birds, reptiles, and amphibians would be initiated to develop baseline information.

Additional staff would include both biological and outreach personnel. A biological technician, outdoor recreation planner, seasonal maintenance worker, and full-time law enforcement officer would be added to accomplish objectives for establishing baseline data on refuge resources, managing habitats, providing opportunities and facilities for wildlife observation and photography, providing educational programs that promote a greater understanding of refuge resources, and protecting natural and cultural resources and refuge visitors.

Under this alternative, the refuge would continue to seek acquisition of all lands within the present acquisition boundary. Lands acquired as part of the refuge would be made available for compatible wildlife-dependent public recreation and environmental education opportunities, where appropriate. Pristine lands that provide high quality habitat and connectivity to existing refuge lands would be priority acquisitions. Equally important acquisition tools to be used include: transfer lands, partnerships with conservation organizations, conservation easements with adjacent landowners, and leases/cooperative agreements with state agencies.

Actions Common to All Alternatives

All three alternatives share the following management concepts and techniques for achieving the goals of the refuge:

- Restoring native habitats;
- Establishing, maintaining, and improving partnerships with landowners and local, state, and federal agencies and organizations;
- Coordinating management actions with local and state land and resource management agencies;
- Monitoring Alabama beach mouse populations and sea turtle nesting in partnership with others;
- Removing non-native invasive plants;
- Encouraging scientific research on the refuge; and
- Continuing land acquisition within the refuge boundary.

DATES: A meeting will be held at the Gulf Shores Adult Activities Center to present the plan to the public. Mailings, newspaper articles, and postings on the refuge Web site will be the avenues to inform the public of the date and time for this meeting. Individuals wishing to comment on the Draft Comprehensive Conservation Plan/Environmental Assessment for Bon Secour National Wildlife Refuge should do so within 30 days following the date of this notice. Public comments were requested, considered, and incorporated throughout the planning process in numerous ways. Public outreach has included public scoping meetings, technical workgroups, planning updates, and a **Federal Register** notice.

ADDRESSES: Requests for copies of the Draft Comprehensive Conservation Plan/Environmental Assessment should be addressed to Robert Cail, Refuge Manager, Bon Secour National Wildlife Refuge, 12295 State Highway 180, Gulf Shores, Alabama 36542. Comments on the draft may be submitted to the above address or via electronic mail to *bonsecour@fws.gov.* Please include your name and return address in your Internet message. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the record, which we will honor to the extent allowable by law.

SUPPLEMENTARY INFORMATION: Bon Secour National Wildlife Refuge is located on the Gulf Coast of Alabama, 8 miles west of the city of Gulf Shores,

Alabama, in Baldwin and Mobile Counties. The refuge is divided into five separate management units along the Fort Morgan Peninsula and Little Dauphin Island. Although the refuge was established in 1980, to date, only 6,978 acres have been acquired within the acquisition boundary totaling approximately 12,570 acres, including the 575 acres leased from the State of Alabama. The Service has management jurisdiction along the shoreline above mean high tide except on Little Dauphin Island, which contains 560 acres of submerged bottoms. The potential wildlife habitat values of beach/dune, maritime forest, and estuarine habitats provided the impetus to purchase the properties.

Management efforts since 1985 have emphasized acquiring land, securing staff to operate the refuge, and initiating conservation programs that benefit endangered wildlife species. However, Service acquisition of key properties, such as inholdings and beach/dune habitat, may not be realized within the 15-year planning period due to budget constraints and landowner preferences. The five units within the acquisition boundary have a significant ''edge,'' which contributes to the predation of birds, sea turtles, and beach mice. Edge effect is the tendency of a transitional zone between communities to support more species and higher population densities than any of the surrounding communities.

Current conservation management projects for the refuge include: recruiting and training staff and improving existing facilities; managing habitats to reduce the threats and problems associated with species of concern; acquiring land to complete refuge boundaries; assisting in sea turtle and Alabama beach mouse recovery; and defining research within the beach/dune area and involving partners and volunteers to accomplish this research.

FOR FURTHER INFORMATION CONTACT: Robert Cail, Refuge Manager, Bon Secour National Wildlife Refuge, telephone: 251/540–7720; fax: 251/540–7301, or mail (write to Refuge Manager at address in **ADDRESSES** section).

Authority: This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997, Pub. L. 105–57.

Dated: January 6, 2005.

Cynthia K. Dohner,

Acting Regional Director.

[FR Doc. 05–2182 Filed 2–3–02; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Preparation of an Environmental Impact Statement for the Joint Water Agency Natural Communities Conservation Plan (NCCP): Subregional Plan and Subarea Plans, San Diego, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), the U.S. Fish and Wildlife Service (Service) advises the public that we intend to gather information necessary to prepare, in coordination with the Joint Water Agency (consisting of Helix Water District, Padre Dam Municipal Water District, Santa Fe Irrigation District, and the Sweetwater Authority) (hereafter collectively referred to as the Applicants), a joint Environmental Impact Statement/Environmental Impact Report (EIS/EIR) for a Natural Communities Conservation Program Subregional Plan (SRP) and three Subarea Plans (SAPs). The combination of the Joint Water Agency SRP and individual SAPs would serve as a multiple species Habitat Conservation Plan under Section 10(a)(1)(B) of the Federal Endangered Species Act, as amended in 1982 (ESA).

The Service provides this notice to: (1) Describe the proposed action and possible alternatives; (2) advise other Federal and State agencies, affected Tribes, and the public of our intent to prepare an EIS/EIR; (3) announce the initiation of a public scoping period; and (4) obtain suggestions and information on the scope of issues and alternatives to be included in the EIS/EIR.

DATES: Public scoping meetings will be held on: Tuesday, February 8, 2005 from 4 p.m. to 7 p.m. and Wednesday, February 9, 2005 from 4 p.m. to 7 p.m. Written comments should be received on or before March 7, 2005.

ADDRESSES: The public meetings will be held at the following locations: (1) Tuesday, February 8, 2005, at the Sweetwater Authority Reynolds Desalination Facility, 3066 North Second Avenue, Chula Vista, CA 91912; and (2) Wednesday, February 9, 2005, at the Padre Dam Municipal Water District Board Room, 10887 Woodside Avenue, Santee, CA 92072.

Information, written comments, or questions related to the preparation of the EIS/EIR and NEPA process should be submitted to Erin Fernandez, Fish and Wildlife Biologist, Carlsbad Fish and Wildlife Office, 6010 Hidden Valley Road, Carlsbad, California 92009 (facsimile 760–431–5902).

FOR FURTHER INFORMATION CONTACT: Erin Fernandez at (760) 431–9440.

SUPPLEMENTARY INFORMATION:

Reasonable Accommodation

Persons needing reasonable accommodations in order to attend and participate in the public meeting should contact Erin Fernandez as soon as possible (see **FOR FURTHER INFORMATION CONTACT**). In order to allow sufficient time to process requests, please call no later than 1 week before the public meeting. Information regarding this proposed action is available in alternative formats upon request.

Background

Section 9 of the Federal ESA (16 U.S.C. 1531 *et seq.*) and Federal regulations prohibit the ''take'' of a fish or wildlife species listed as endangered or threatened. Under the ESA, the following activities are defined as take: harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect listed animal species, or attempt to engage in such conduct (16 U.S.C. 1538). However, under section 10(a) of the ESA, we may issue permits to authorize ''incidental take'' of listed species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing permits for threatened species and endangered species, respectively, are at 50 CFR 17.32 and 50 CFR 17.22.

Take of listed plant species is not prohibited under the ESA and cannot be authorized under a section 10 permit. We propose to include plant species on the permit in recognition of the conservation benefits provided for them under the plan.

The purpose of the EIS/EIR is to analyze the impacts of the proposed implementation of the SRP and three SAPs. The Federal need for the SRP and three SAPs is to meet the criteria for incidental take authorization of species on the covered species list.

The proposed SRP would comprehensively address how participating water agencies will manage their lands to conserve natural habitats and species while continuing to provide their mandated water services to the public. The proposed SRP would serve as an ''umbrella document'' to guide the preparation of Natural Communities Conservation Program subarea plans by each participating water agency. The combination of the

Joint Water Agency SRP and individual SAPs would serve as a multiple species Habitat Conservation Plan under Section 10(a)(1)(B) of the Federal ESA.

The Service and the California Department of Fish and Game may issue take authorization permits for individual SAPs with conditions or modifications. The proposed SRP would consist of several key components including an implementation process and structure, preserve management guidelines, and a covered species list. A total of 80 species are proposed for coverage under the SRP. The proposed SRP would strive to anticipate and cover the effects on biological resources of all currently foreseeable actions of the participating water agencies over the next 75 years. The proposed SRP would address the following groups of foreseeable projects and covered actions: facilities operation and maintenance, planned or conceptual projects, and potential future projects.

The proposed planning area encompasses approximately 8,600 acres (13.5 square miles) of land in northern, eastern, and southern San Diego County cumulatively owned by the participating water agencies. These lands are located in the unincorporated County area, and in the cities of Santee, El Cajon, La Mesa, and Chula Vista. In general, ownerships consist of land used directly for water production, collection, storage, treatment, and distribution as well as easements used primarily for water and wastewater distribution pipelines. These facilities consist of open water reservoirs, water tanks, water, reclaimed water, and wastewater treatment plants, pump stations, pipelines, and access roads. In addition, the agencies also have maintenance trails and roadways, maintenance yards, and sedimentation ponds. In some situations, watershed protection lands provide recreational facilities, including camp grounds, golf courses, boat docks and ramps, fishing piers, hiking trails, and interpretive signage. These lands are operated in cooperation with other agencies such as the County and City of San Diego.

Components of the proposed conservation program are now under consideration by the Service and the Applicants. These components will likely include avoidance and minimization measures, monitoring, adaptive management, and mitigation measures consisting of preservation, restoration, and enhancement of habitat.

Environmental Impact Statement/ Environmental Impact Report

The Applicants, the Service, and the California Department of Fish and Game have selected A.D. Hinshaw Associates to prepare the Draft EIS/EIR. The joint document will be prepared in compliance with NEPA and the California Environmental Quality Act (CEQA). Although A.D. Hinshaw Associates will prepare the EIS/EIR, the Service will be responsible for the scope and content of the document for NEPA purposes, and the Sweetwater Authority will be responsible for the scope and content of the EIR for CEQA purposes.

The EIS/EIR will consider the proposed action (i.e., the issuance of a section 10(a)(1)(B) permit under the Federal ESA), and a reasonable range of alternatives. A detailed description of the proposed action and alternatives will be included in the EIS/EIR. It is anticipated that several alternatives will be developed, which may vary by the level of conservation, impacts caused by the proposed activities, permit area, covered species, or a combination of these factors. Additionally, a No Action alternative will be considered. Under the No Action alternative, the Service would not issue a section 10(a)(1)(B) permit.

The EIS/EIR will also identify potentially significant impacts on biological resources, recreation, and other environmental issues that could occur directly or indirectly with implementation of the proposed action and alternatives. For all potentially significant impacts, the EIS/EIR will identify mitigation measures where feasible to reduce these impacts to a level below significance.

Environmental review of the EIS/EIR will be conducted in accordance with the requirements of NEPA (42 U.S.C. 4321 *et seq.*), its implementing regulations (40 CFR 1500–1508), other applicable regulations, and Service procedures for compliance with those regulations. This notice is being furnished in accordance with 40 CFR 1501.7 of NEPA to obtain suggestions and information from other agencies and the public on the scope of issues and alternatives to be addressed in the EIS/EIR. The primary purpose of the scoping process is to identify important issues raised by the public, related to the proposed action. Written comments from interested parties are invited to ensure that the full range of issues related to the proposed action is identified. While written comments are encouraged, we will accept both written and oral comments at the public meeting. In addition, you may submit written comments by mail or facsimile transmission (see **ADDRESSES**). All comments received, including names and addresses, will become part of the official administrative record, and may be made available to the public.

Dated: January 31, 2005.

Ken McDermond,

Deputy Manager, California/Nevada Operations Office, Sacramento, California.

[FR Doc. 05–2141 Filed 2–3–05; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–020–05–1610–DO–036E]

Notice of Intent To Prepare a Resource Management Plan Revision and Environmental Impact Statement for Eastern Montana

AGENCY: Bureau of Land Management, Interior, Montana, Miles City Field Office.

ACTION: Notice of intent to prepare a Resource Management Plan Revision and Environmental Impact Statement for Eastern Montana, initiate public scoping and request comments on Planning Criteria.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701), as amended; the National Environmental Policy Act of 1969 (42 U.S.C. 4321), as amended; and the Council on Environmental Quality (CEQ) regulations (40 CFR parts 1500–1508), the Bureau of Land Management (BLM) will revise two Resource Management Plans (RMPs) by combining the Powder River and Big Dry RMPs (to be called the ''Miles City Field Office RMP'') and preparing an Environmental Impact Statement (EIS) to evaluate the effects of land and mineral management options. The RMP and EIS are scheduled for completion by December 2007.

DATES: Written and electronic comments on the scope of the RMP, preliminary issues, and planning criteria may be submitted for 30 days from the date of this notice. Public scoping meetings will be held in Ashland, Baker, Broadus, Glendive, Jordan, Miles City, Terry, Billings and Sidney, Montana. Meeting locations and dates for each town will be announced through local news media, newsletters and the BLM public outreach Web site *http://www.mt.blm.gov/mcfo/.*

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

Web site: http://milescityrmp.com.

Mail: ''Miles City RMP Comments'', P.O. Box 219, Miles City, MT 59301–0219.

Fax: (918) 382–7582.

Hand-Deliver: Miles City Field Office, 111 Garryowen Road, Miles City, Montana.

Comments on issues and planning criteria may also be submitted to the BLM at any public scoping meeting. Documents pertinent to the Miles City Field Office RMP may be examined at the Miles City Field Office, 111 Garryowen Road, Miles City, MT.

FOR FURTHER INFORMATION CONTACT: Mary Bloom, Project Manager, Bureau of Land Management, Miles City Field Office, 111 Garryowen Road, Miles City, MT, telephone (406) 233–2852. Web site questions may be directed to *WebSiteAdmin@milescityrmp.com.*

SUPPLEMENTARY INFORMATION: The approved RMP will replace the existing Big Dry and Powder River RMPs as the document guiding land and resource management decisions on BLM-administered lands and minerals in the planning area. The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis and alternatives. These issues also guide the planning process. The BLM will work collaboratively with interested parties to identify the management options that are best suited to local, regional, and national needs and concerns. Public land management within the planning area is currently guided by the Big Dry RMP and the Powder River RMP, completed in 1996 and 1985, respectively.

The intent of the planning process is to analyze and update land and resource management objectives within the planning area. The planning area includes all of the BLM-administered surface (2,785,000 acres) and mineral (11,725,000 acres) estate managed by the Miles City Field Office in Carter, Custer, Daniels, Dawson, Fallon, Garfield, McCone, Powder River, Prairie, Richland, Roosevelt, Rosebud, Sheridan, Treasure, Wibaux and portions of Big Horn and Valley counties.

The public will assist the BLM in identifying the issues. Preliminary issues and management concerns have been identified by BLM personnel and other agencies, and in meetings with individuals and user groups. The RMP will consider resource options that are scientifically sound, legally defensible and sustainable. Examples of preliminary issues include the need to provide access to significant energy sources and communication sites, the continuation of grazing activities, maximizing use of public lands in species recovery and habitat conservation, and the need to provide adequate facilities for safe recreation and visitation on the public lands. Topics to be addressed in the RMP will include vegetation; forestry and timber; special status species; water quality and quantity; travel management; all special management area designations; livestock grazing; fluid mineral leasing, including for coal bed natural gas; solid minerals; recreational uses; right-of-way corridor planning and land authorizations; land tenure adjustment information and access needs; and Native American concerns. Management concerns include air quality, cultural resources, paleontological resources, social and economic concerns, environmental justice, and wildfire management. BLM will also consider compatibility with management plans for adjacent lands.

BLM is also extending a call for coal resource information and any information regarding resources which may affect the leasing of Federal coal or be affected by the leasing of Federal coal. Resource information pertinent to any other BLM resource management activities is also requested.

The RMP and EIS will be prepared by an interdisciplinary team with specialists for recreation, fisheries, biology, archeology, air quality, wildlife, realty, geology and mining, and range management.

Please note that comments and information submitted regarding this RMP, including names, e-mail addresses, and street addresses of respondents, will be available for public review and disclosure at the above address. BLM will not accept anonymous comments. Individual respondents may request confidentiality. Individuals who wish to withhold their name or street address from public review or from disclosure under the Freedom of Information Act must state this prominently at the beginning of their written comments. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

Dated: January 5, 2005.

David McIlnay,

Field Manager.

[FR Doc. 05–2111 Filed 2–3–05; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Glen Canyon Dam Adaptive Management Work Group (AMWG), Notice of Meeting

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public meeting.

SUMMARY: The Adaptive Management Program (AMP) was implemented as a result of the Record of Decision on the Operation of Glen Canyon Dam Final Environmental Impact Statement to comply with consultation requirements of the Grand Canyon Protection Act (Pub. L. 102–575) of 1992. The AMP includes a federal advisory committee (AMWG), a technical work group (TWG), a monitoring and research center, and independent review panels. The AMWG makes recommendations to the Secretary of the Interior concerning Glen Canyon Dam operations and other management actions to protect resources downstream of Glen Canyon Dam consistent with the Grand Canyon Protection Act. The TWG is a subcommittee of the AMWG and provides technical advice and recommendations to the AMWG.

Date and Location: The AMWG will conduct the following public meeting:

Phoenix, Arizona—March 2–3, 2005. The meeting will begin at 10 a.m. and conclude at 5 p.m. on the first day and will begin at 8 a.m. and conclude at 3 p.m. on the second day. The meeting will be held at the Arizona Department of Water Resources, 500 N. Third Street, Conference Rooms A&B, Phoenix, Arizona.

Agenda: The purpose of the meeting will be to review the Fiscal Year 2004 budget expenditures, the FY06 Draft Budget and Work Plan, updates on plans currently in development, and other monitoring and research reports. Other topics of discussion will include status of the Colorado River Basin Fund, Programmatic Agreement membership, basin hydrology, the Humpback Chub Comprehensive Plan, public outreach, environmental compliance progress on proposed actions, as well as other administrative and resource issues pertaining to the AMP.

Time will be allowed for any individual or organization wishing to make formal oral comments (limited to 5 minutes) at the meeting. To allow full consideration of information by the AMWG members, written notice must be provided to Dennis Kubly, Bureau of Reclamation, Upper Colorado Regional Office, 125 South State Street, Room

6107, Salt Lake City, Utah, 84138; telephone (801) 524–3715; faxogram (801) 524–3858; e-mail at *dkubly@uc.usbr.gov* at least five (5) days prior to the meeting. Any written comments received will be provided to the AMWG and TWG members.

FOR FURTHER INFORMATION CONTACT: Dennis Kubly, telephone (801) 524–3715; faxogram (801) 524–3858; or via e-mail at *dkubly@uc.usbr.gov*.

Dated: January 24, 2005.

Randall V. Peterson,

Manager, Environmental Resources Division, Upper Colorado Regional Office, Salt Lake City, Utah.

[FR Doc. 05–2142 Filed 2–3–05; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Black Mesa and Kayenta Mines, Life-of-Mine Plans and Water Supply Project, Coconino, Navajo, and Mohave Counties, AZ, and Clark County, NV

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Extension of the scoping comment period for an environmental impact statement.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (NEPA), the Office of Surface Mining Reclamation and Enforcement (OSM) is extending the scoping comment period for the Black Mesa Project environmental impact statement (EIS). The Black Mesa Project includes Peabody Western Coal Company's proposed operation and reclamation plans for the Black Mesa and Kayenta coal mines; the Coal Slurry Preparation Plant at the Black Mesa Mine; the reconstruction of the 273-mile long Coal Slurry Pipeline across northern Arizona from the Coal Slurry Preparation Plant to the Mohave Generating Station (electrical) in Laughlin, Nevada; the construction and operation of water wells in the Coconino aquifer (C-aquifer) northwest of Winslow, Arizona; and construction and operation of a water supply pipeline running about 120 miles across the Navajo and Hopi Reservations from the wells to the Coal Slurry Preparation Plant.

DATES: Written comments must be received by OSM by 4 p.m. on March 4, 2005, to ensure consideration in the preparation of the draft EIS.

ADDRESSES: Comments may be submitted in writing or by e-mail. At the top of your letter or in the subject line of your e-mail message, please indicate that the comments are ''BMK EIS Comments.''

- E-mail comments should be sent to: *BMK-EIS@osmre.gov*.
- Written comments sent by first-class or priority U.S. Postal Service should be mailed to: Richard Holbrook, Chief, Southwest Branch, OSM WRCC, P.O. Box 46667, Denver, Colorado 80201–6667
- Comments delivered by U.S. Postal Service Express Mail or by courier service should be sent to: Richard Holbrook, Chief, Southwest Branch OSM WRCC, 1999 Broadway, Suite 3320, Denver, Colorado 80202–5733

FOR FURTHER INFORMATION CONTACT: Richard Holbrook, Chief, Southwest Branch, Program Support Division, OSM Western Regional Coordinating Center, by telephone at (303) 844–1400, extension 1491, or by e-mail at *BMK-EIS@osmre.gov*.

SUPPLEMENTARY INFORMATION: On December 1, 2004, OSM published in the **Federal Register** a notice of intent to prepare an EIS for the Black Mesa Project and to hold public scoping meetings (69 FR 69951).

OSM held eight scoping meetings to solicit public comments on the scope of the EIS and significant issues that should be addressed in the EIS. Due to the complex nature of the project and numerous concerns expressed during the scoping meetings, OSM is extending the scoping comment period.

The Black Mesa Project includes Peabody Western Coal Company's proposed operation and reclamation plans for the Black Mesa and Kayenta coal mines; the Coal Slurry Preparation Plant at the Black Mesa Mine; the reconstruction of the 273-mile long Coal Slurry Pipeline across northern Arizona from the Coal Slurry Preparation Plant to the Mohave Generating Station (electrical) in Laughlin, Nevada; the construction and operation of water wells in the Coconino aquifer (C-aquifer) northwest of Winslow, Arizona; and construction and operation of a water supply pipeline running about 120 miles across the Navajo and Hopi Reservations from the wells to the Coal Slurry Preparation Plant. At *www.wrcc.osmre.gov/bmk-eis*, interested persons may view information about the proposed projects.

In accordance with the Council on Environmental Quality's regulations for implementing NEPA, 40 CFR Parts 1500 through 1508, OSM solicits public comments on the scope of the EIS and significant issues that it should address in the EIS.

Written comments, including email comments, should be sent to OSM at the addresses given in the **ADDRESSES** section of this notice. Comments should be specific and pertain only to the issues relating to the proposals. OSM will include all comments in the administrative record.

If you would like to be placed on the mailing list to receive future information, please contact the person listed in the section, **FOR FURTHER INFORMATION CONTACT**, above.

OSM will make comments, including names and addresses of respondents, available for public review during normal business hours. OSM will not consider anonymous comments. If individual respondents request confidentiality, OSM will honor their requests to the extent allowable by law. Individual respondents who wish to withhold their name or address (except for the city or town) from public review must state this prominently at the beginning of their comments and must submit their comments by regular mail. All submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses will be available for public review in their entirety.

Dated: January 27, 2005.

Allen D. Klein,

Regional Director, Western Regional Coordinating Center.

[FR Doc. 05–2180 Filed 2–3–05; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–101 (Second Review)]

Greige Polyester/Cotton Printcloth From China

AGENCY: United States International Trade Commission.

ACTION: Revised schedule for the subject review.

EFFECTIVE DATE: January 28, 2005.

FOR FURTHER INFORMATION CONTACT: Gail Burns (202–205–2501), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special

assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION: Effective August 25, 2004, the Commission established a schedule for the conduct of the subject review (69 FR 53465, September 1, 2004). As a result of a scheduling conflict, however, the Commission is revising its schedule; the Commission's hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on April 1, 2005. The Commission's original schedule is otherwise unchanged. No party has objected to the Commission's schedule, as revised.

For further information concerning this review see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

Issued: January 31, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–2150 Filed 2–3–05; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Office of Special Counsel for Immigration Related Unfair Employment Practices; Immigration Related Employment Discrimination Public Education Grants

AGENCY: Office of Special Counsel for Immigration Related Unfair Employment Practices, Civil Rights Division, U.S. Department of Justice.

ACTION: Notice of availability of funds and solicitation for grant applications.

SUMMARY: The Office of Special Counsel for Immigration Related Unfair Employment Practices (OSC) announces the availability of funds for grants to conduct public education programs about the rights afforded potential victims of employment discrimination and the responsibilities of employers under the anti-discrimination provision of the Immigration and Nationality Act (INA), 8 U.S.C. 1324b. It is anticipated that a number of grants will be competitively awarded to applicants who can demonstrate a capacity to design and successfully implement public education campaigns to address immigration related unfair employment discrimination. Grants may range in size from $35,000 to $100,000. Applicants must demonstrate the ability to educate workers, employers and/or the general public about the anti-discrimination provision of the INA. OSC welcomes proposals from diverse public service groups, organizations or associations providing information services to employers and/or potential victims of discrimination, and Faith-Based organizations, non-profit groups providing services and assistance to potential victims of discrimination.

DATES: *Application Due Date:* March 21, 2005.

FOR FURTHER INFORMATION CONTACT: Lilia Irizarry, Acting Public Affairs Specialist, Office of Special Counsel for Immigration Related Unfair Employment Practices, 950 Pennsylvania Ave., Washington, DC 20530. Tel. (202) 616–5594, or (202) 616–5525 (TDD for the hearing impaired).

SUPPLEMENTARY INFORMATION: The Office of Special Counsel for Immigration Related Unfair Employment Practices of the Civil Rights Division of the Department of Justice announces the availability of funds to conduct cost effective public education programs concerning the anti-discrimination provision of the INA. Funds will be awarded to selected applicants who propose cost-effective ways of educating employers, workers covered by this statute, community service providers, and/or the general public.

Background: The Immigration and Nationality Act protects work authorized individuals from employment discrimination based on their citizenship status and/or national origin. Federal law also makes knowingly hiring unauthorized workers unlawful, and requires employers to verify the identity and employment eligibility of all new employees. Employers who violate this law are subject to sanctions, including fines and possible criminal prosecution. Employers of four or more employees are prohibited from discriminating on the basis of citizenship status or national origin with respect to hiring, firing, recruitment or referral for a fee. They are also prohibited from committing ''document abuse'' on the basis of national origin or citizenship status in the employment eligibility verification process. U.S. citizens and certain classes of work authorized individuals are protected from citizenship status discrimination. Protected non-citizens include:

- Legal Permanent Residents;
- Refugees;
- Asylees; and
- Temporary Residents.

Citizens and all work authorized individuals are protected from discrimination on the basis of national origin. However, under the INA the prohibition against national origin discrimination applies only to employers with four to fourteen employees. National origin discrimination complaints against employers with fifteen or more employees fall under the jurisdiction of the Equal Employment Opportunity Commission pursuant to Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e, *et seq.* In addition, under the document abuse provision of the law, employers cannot request more or different documents than are required for completion of the Employment Eligibility Verification (I–9) Form, prefer or require one form of documentation over another, or refuse documents that appear reasonably genuine on their face, if made for the purpose or with the intent of discriminating against an individual on the basis of national origin or citizenship status. OSC is responsible for receiving and investigating discrimination charges and, when appropriate, filing complaints with specially designated administrative law judges. OSC also initiates independent investigations of possible immigration-related job discrimination. While OSC has established a record of vigorous enforcement, studies have shown that there is an extensive lack of knowledge on the part of protected individuals and employers about the anti-discrimination provision of the INA. Enforcement cannot be effective if potential victims of discrimination are not aware of their rights. Moreover, discrimination can never be eradicated so long as employers are not aware of their responsibilities.

Purpose: OSC seeks to educate both workers and employers about their rights and responsibilities under the anti-discrimination provision of the INA. Applicants must demonstrate the ability to use diverse forms of mass and electronic media to educate employers and/or employees [in both the public and private sectors], as well as agencies providing services to potential victims concerning the anti-discrimination provision of the INA. OSC seeks proposals that will use existing

materials or propose to develop additional materials to effectively educate employees and/or employers about exercising their rights or fulfilling their obligations under the anti-discrimination provision. OSC will consider any proposal that articulates and substantiates other creative means of reaching these populations, including, for example, the use of creative media public service announcements for local communities, non-profits organizations and business groups.

Program Description: The program is designed to develop and implement cost-effective approaches to educate potential victims of employment discrimination about their rights and to educate employers about their responsibilities under INA's anti-discrimination provision. Applications may propose to educate potential victims only, employers only, or both in a single campaign. Program budgets must include the travel, lodging and other expenses necessary for up to two program staff members to attend the mandatory OSC grantee training (2 days) that will be held in Washington, DC. Proposals should outline the following key elements of the program:

Part I: Intended Audience(s)

The educational efforts under the grant should be directed to: (1) Work authorized and protected non-citizens, (2) citizens at the risk of becoming victims of employment discrimination; and/or (3) employers, especially those in both large and small businesses and industries that employ large numbers of individuals in categories (1) and (2). The proposals should define the characteristics of the work authorized population or the employer group(s) intended to be the focus of the educational campaign. It must also identify the applicant's qualifications to reach credibly and effectively large segments of the intended audience(s). The proposals should detail the reasons for focusing on each group of protected individuals or employers by describing particular needs or other factors to support the selection. In defining the campaign focuses and supporting the reasons for the selection, applicants may use census data, studies, surveys, or any other sources of information of generally accepted reliability.

Part II: Campaign Strategy

We encourage applicants to devise effective and creative means of public education and information dissemination that are specifically designed to reach the widest possible intended audience. Those applicants proposing educational campaigns addressing potential victims of discrimination should keep in mind that some of the traditional methods of public communication may be less than optimal for educating members of national origin or linguistic groups that have limited community-based support and communication networks. Grants are an important component of OSC partnerships to better serve the public, employers and potential discrimination victims. Grantees should plan to include OSC attorneys and other professional staff in public outreach programs in order to more successfully reach their audiences and prevent discrimination before it occurs or combat it where it exists. Proposals should discuss the components of the campaign strategy, detail the reasons supporting the choice of each component, and explain how each component will effectively contribute to the overall objective of cost-effective dissemination of useful and accurate information to a wide audience of protected individuals or employers. Discussions of the campaign strategies and supporting rationale should be clear, concise, and based on sound evidence and reasoning. Budget proposals should include the costs for distribution of materials received from OSC or from current/past OSC grantees. To the extent that applicants believe the development of original materials particularly suited to their campaign is necessary, their proposal should articulate in detail the circumstances requiring the development of such materials. All such materials must be approved by OSC prior to production to ensure legal accuracy and proper emphasis. Proposed revisions/translations of OSC-approved materials must also be submitted for clearance. All information distributed should also identify OSC as a source of assistance, information and action, and include the correct address and telephone numbers of OSC (including the toll-free numbers, TDD numbers), and OSC e-mail and Internet addresses.

Part III: Evaluation of the Strategy

A full evaluation of a project's effectiveness is due within 60 days of the conclusion of a campaign. Interim evaluation/activity reports are due quarterly.

Selection Criteria: The selection of grantees for award will be made by the Special Counsel for Immigration Related Unfair Employment Practices. A panel comprised of OSC staff will review and rate the applications and make recommendations to the Special Counsel regarding funding. The panel's results are advisory in nature and not binding. *Letters of support, endorsement, or recommendation are not part of the grant application process and will not be considered.* In determining which applications to recommend, OSC staff, based on a one hundred point scale will consider the following:

1. Program Design (50 points). Sound program design and cost-effective strategies for educating the intended population are imperative. Consequently, areas that will be closely examined include the following:

a. Demonstration of a clear understanding of the requirements of the anti-discrimination provision of the Immigration and Nationality Act and the Special Counsel's outreach goals. (10 points)

b. Clear statement of the proposed goals and objectives, including a listing of the major events, activities, products and timetables for completion and the extent of OSC participation in grantee outreach events. (10 points)

c. Selection and definition of the intended audience(s) for the campaign, and the factors that support the selection, including special needs, and the applicant's qualifications to reach effectively the intended audience(s). (10 points)

d. A cost-effective campaign strategy for educating employers and/or members of the protected class, with a justification for the choice of strategy. (10 points)

e. How the applicant proposes to measure the effectiveness and success of the education campaign. (10 points).

2. Administrative Capability (20 points). Proposals will be rated in terms of the capability of the applicant to define the intended audience, reach it, and implement the public education and evaluation components of the campaign:

a. Evidence of proven ability to provide high quality results in the public outreach program. (10 points)

b. Evidence that the applicant can implement the campaign. (10 points)

Note: OSC's experience during previous grant cycles has shown that a number of applicants choose to apply as a consortium of individual entities; or, if applying individually, propose the use of subcontractors to undertake certain limited functions. It is essential that these applicants demonstrate the proven management capability and experience to ensure that, as lead agency, they will be directly accountable for the successful implementation, completion, and evaluation of the project.

3. Staff Capability (10 points). Applications will be evaluated in terms of the degree to which:

a. The duties outlined in the proposed staffing plan for grant-funded positions

appear appropriate to the work that will be conducted under the award. (5 points)

b. The qualifications of the grant funded positions appear to match the requirements of these positions. (5 points)

Note: If the grant project manager or other member of the professional staff is to be hired later as part of the grant, or should there be any change in professional staff during the grant period, hiring is subject to review and approval by OSC at that time.

4. Service to Underserved Communities (20 points). OSC has determined a need to reach out to groups and communities previously underserved, or not served at all, by this grant program or by comparable service providers. This includes identifying employers and employees organizations, faith based groups, non-profit and public service groups or other communities not previously served. It also includes identifying employers and employer organizations with whom the program has not previously interacted. This need is particularly relevant in light of recent world events which have raised the possibility of immigration-status discrimination for groups that may not have previously been subject to such conduct. Applicants should identify groups or communities served by their proposed program, which may be categorized as previously under served. When developing their proposals and budgets and conducting their programs and activities grantee should consider the need for language services for limited English proficient (LEP) persons served or encountered. The Department of Justice has determined that costs associated with providing meaningful access for LEP individuals are considered allowable program cost.

Eligible Applicants: This grant competition is open to all applicants including labor and immigrant organizations, small and large businesses and associations, employer groups and associations, public service or community-based organizations, faith-based organizations and state and local government agencies.

Grant Period and Award Amount: It is anticipated that several grants will be awarded and may range in size from $35,000 to $100,000. Publication of this announcement does not require OSC to award any specific number of grants, or to obligate all or any part of available funds. The period of performance will be twelve months from the date of the grant award.

Application Deadline: All applications must be postmarked by March 21, 2005. If using regular first classmail, send to: U.S. Department of Justice, Civil Rights Division, Office of Special Counsel for Immigration Related Unfair Employment Practices, 950 Pennsylvania Avenue, NW., Washington, DC 20530. If using messengers, overnight or priority mail—which OSC encourages due to delays in the delivery of regular mail—send to: Office of Special Counsel for Immigration Related Unfair Employment Practices, U.S. Department of Justice, 1425 New York Ave., NW., Suite 9000, Washington, DC 20005. *Applications may not be submitted via facsimile machine.*

Application Requirements: Applicants should submit an original and two (2) copies of their completed proposal by the deadline established above. All submissions must contain the following items in the order listed below:

1. A completed and signed Application for Federal Assistance (Standard Form 424).

Note: The Catalogue of Federal Domestic Assistance number is 16.110 and the title is: ''Education & Enforcement of the Antidiscrimination provision of the Immigration and Nationality Act'' (box #10 of the SF 424).

2. OJP Form 4061/6 (Certification Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and Drug-Free Workplace Requirements).

3. Disclosure Form to Report Lobbying (SF LLL)

4. OJP Form 4000/3 (Assurances)

5. An abstract of the full proposal, not to exceed one page.

6. A program narrative of not more than fifteen (15) double-spaced typed pages that clearly and specifically demonstrates how the applicant meets each of the four (4) elements set forth as Selection Criteria, above.

7. A proposed budget outlining all direct and indirect costs for personnel, fringe benefits, travel, equipment, supplies, subcontracts, and a short narrative justification of each budgeted line item cost. If an indirect cost rate is used in the budget, then a copy of a current fully executed agreement between the applicant and the cognizant Federal agency must accompany the budget.

Note: Program budgets must include the travel, lodging and other expenses necessary for not more than two program staff members to attend the mandatory OSC grantee training (2 days) that will be held in Washington, DC, at the end of September.

8. Copies of resumes of the professional staff proposed in the budget. Application forms may be obtained by writing or telephoning: U.S. Department of Justice, Civil Rights Division, Office of Special Counsel for Immigration Related Unfair Employment Practices, 950 Pennsylvania Avenue, NW., Washington, DC 20530. Tel. (202) 616–5594, or (202) 616–5525 (TDD for the hearing impaired). This announcement and the required forms will also appear on the World Wide Web at: *http://www.usdoj.gov/crt/osc.* In order to facilitate handling, please do not use covers, binders or tabs.

Dated: January 31, 2005.

William J. Sanchez,

Special Counsel for Immigration Related Unfair Employment Practices.

[FR Doc. 05–2132 Filed 2–3–05; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Accredited Standards Committee N–13 on Radiation Protection

Notice is hereby given that, on September 27, 2004, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Accredited Standards Committee N–13 on Radiation Protection (''N–13'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the name and principal place of business of the standards development organization is: Accredited Standards Committee N–13 on Radiation Protection, McLean, VA. The nature and scope of N–13's standards development activities are: the development of national standards dealing with or pertaining to radiation protection and the protection of individuals or groups from occupational or environmental

exposure to radiation or radioactive materials.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–2161 Filed 2–3–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—American Board of Orthopaedic Surgery

Notice is hereby given that, on September 20, 2004, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.c. 4301 *et seq.* (''the Act''), American Board of Orthopaedic Surgery (''ABOS'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the name and principal place of business of the standards development organization is: American Board of Orthopaedic Surgery, Chapel Hill, NC. The nature and scope of ABOS's standards development activities are: Development of educational standards and standards for evaluating the qualifications and knowledge of physicians seeking voluntary certification in orthopaedic surgery.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–2159 Filed 2–3–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—American Forest & Paper Association

Notice is hereby given that, on September 20, 2004, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), American Forest & Paper Association (''AF&PA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the name and principal place of business of the standards development organization is: American Forest & Paper Association, Washington, DC. The nature and scope of AF&PA's standards development activities are: to develop and maintain standards for the structural design of wood products and their connectors.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–2162 Filed 2–3–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—National Registry of Emergency Medical Technicians

Notice is hereby given that, on September 20, 2004, pursuant to Section 6(a) of the National Cooperative Research and Production act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), National Registry of Emergency Medical Technicians (''NREMT'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the name and principal place of business of the standards development organization is: National Registry of Emergency Medical Technicians, Columbus, OH. The nature and scope of NREMT's standards development activities are: Development of uniform standards for training and examination of personnel active in the delivery of emergency medical services.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–2160 Filed 2–3–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

January 28, 2005.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Office of the Assistant Secretary for Policy.

Type of Review: New collection of information.

Title: Information Collection Request for the Assessment of Compliance Assistance Activities Generic Clearance.

OMB Number: 1225–0NEW.

Frequency: On occasion.

Type of Response: Reporting.

Affected Public: Business or other for-profit; Not-for-profit institutions; Farms; Individuals or households; State, local, or tribal government; and Federal Government.

Number of Respondents: 9,998.

Number of Annual Respondents: 9,998.

Average Response Time: Phone survey—15 minutes; Mail survey—15 minutes; Onsite revisit—120 minutes; and On-line survey—10 minutes.

Estimated Annual Burden Hours: 2,202.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $0.

Description: DOL proposes to assess and measure self-reported changes in behavior through surveys of workers, employers and other stakeholders. These surveys will provide feedback on compliance assistance documents and materials, onsite consultation visits, telephone and technical assistance, Web sites, partnerships and alliances, and compliance assistance seminars and workshops delivered by DOL across the country to the regulated community. This feedback will help DOL agencies improve the future quality and delivery of compliance assistance tools and services.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–2189 Filed 2–3–05; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

January 31, 2005.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation contact Ira Mills on (202) 693–4122 or e-mail: *Mills.Ira@dol.gov*.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ETA, Office of Management and Budget, Room 10235, Washington, DC 20503 (202) 395–7316 (this is not a toll-free number), within 30 days from the data of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: Extension of a currently approved collection.

Title: Employment and Training Administration Disaster Unemployment Assistance (DUA) Handbook and Operating Forms, Including ETA–90–2, Disaster Payment Activities Under the ''Stafford Disaster Relief Act''.

OMB Number: 1205–0051.

Affected Public: Individuals or households; Federal government; and State, local, or tribal government.

Type of Response: Recordkeeping and reporting.

Frequency: On occasion; monthly; weekly; and bi-weekly.

Form	Respondents	Reports filed annually (frequency)	Total annual responses	Average response time (hours)	Annual burden hours
SF 269A	50	6	300	1.5	450
ETA–902	50	6	300	1/6	50
Initial Applications (Includes processing, determining eligibility, issuing notices, recordkeeping, etc.)	***11,000	1	11,000	1/6	1,833
Supplemental to Initial Application (Self-empl.)	3,800	1	3,800	1/6	633
Weekly claim includes processing, determining eligibility, issuing adjustment notices, recordkeeping, etc.)	11,000	*6	66,000	1/12	5,500
Notice of Overpayment	235	1	235	1/4	59
Final Report	50	1	50	1	50
Cost/Expense	50	(**)	75	1/4	19
Miscellaneous Recordkeeping	50	n/a	81,335	1/40	2,033
Total	26,235		162,795		10,627

* This figure represents an *average* number of weeks of unemployment experienced (weeks paid) due to disasters declared each year.
**Represent 50 initial cost/expense reports and 25 supplemental reports.
***Rounded.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: The information collection requirements contained in Employment and Training Handbook No. 356, 2nd Edition, ''Disaster Unemployment Assistance,'' are necessary for the administration of Sections 410 and 423 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Act). Workload items are also used with fiscal reports to

estimate the cost of administering the Act.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–2190 Filed 2–3–05; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

January 27, 2005.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension of currently approved collection.

Title: Fire Brigades (29 CFR 1910.156).

OMB Number: 1218–0075.

Frequency: On occasion.

Type of Response: Recordkeeping and Third party disclosure.

Affected Public: Business or other for-profit; Not-for-profit institutions; Federal Government; and State, local, or tribal government.

Number of Respondents: 8,391.

Number of Annual Responses: 8,391.

Estimated Time Per Response: 5 minutes to obtain a physician's certificate and 2 hours to develop or revise organizational statements for fire brigades.

Total Burden Hours: 6,042.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $0.

Description: Although OSHA does not mandate that employers establish fire brigades, 29 CFR 1910.156 (the Standard) requires an employer who does establish a fire brigade to write an organizational statement; obtain a physician's certificate of fitness for employees with specific physical conditions to participate in fire-related operations; and provide appropriate training and information to fire brigade members. The provisions of the Standard apply to fire brigades, industrial fire departments, and private or contract fire departments, but not to airport crash-rescue units or forest fire-fighting operations. The Standard serves to protect the occupational health and safety of employees who participate in fire brigades.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension of currently approved collection.

Title: Voluntary Protection Program Information.

OMB Number: 1218–0239.

Frequency: On occasion; Annually; Quarterly; and Every three years.

Type of Response: Reporting.

Affected Public: Business or other for-profit; Not-for-profit institutions; Federal Government; State, local, or tribal government; and Individuals or households.

Number of Respondents: 1,566.

Number of Annual Responses: 1,874.

Estimated Time Per Response: Varies from 200 hours to prepare an application to 8 minutes to complete a general eligibility information sheet.

Total Burden Hours: 86,900.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $0.

Description: The Voluntary Protection Programs (VPP) established the efficacy of cooperative action among government, industry, and labor to address worker safety and health issues and to expand worker protection. To qualify, employers must meet OSHA's rigorous safety and health management criteria which focus on comprehensive management systems and active employee involvement to prevent or control worksite safety and health hazards.

The information collection requirements associated with the VPP include various application requirements, quarterly and annual reports as well as annual evaluations. The information collected on applications helps applicants and OSHA ensure that potential participants qualify for the program. The information collected by quarterly and annual reports and annual evaluations help participants and OSHA determine the effectiveness of the program.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–2191 Filed 2–3–05; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

January 26, 2005.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on (202) 693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employee Benefits Security Administration (EBSA), Office of Management and Budget, Room 10235, Washington, DC 20503, (202) 395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register.**

The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: Employee Benefits Security Administration.

Type of Review: Extension of currently approved collection.

Title: Class Exemption 81–8 for Investment of Plan Assets in Certain Types of Short-Term Investments.

OMB Number: 1210–0061.

Frequency: On occasion.

Type of Response: Third party disclosure.

Affected Public: Business or other for-profit; not-for-profit institutions; and individuals or households.

Number of Respondents: 46,000.

Number of Annual Responses: 230,000.

Estimated Time per Response: 10 minutes.

Total Burden Hours: 38,300.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $85,100.

Description: Prohibited Transaction Class Exemption 81–8 permits the investment of plan assets that involve the purchase or other acquisition, holding, sale, exchange or redemption by or on behalf of an employee benefit plan in certain types of short-term investments. These include investments in banker's acceptances, commercial paper, repurchase agreements, certificates of deposit, and bank securities. Absent the exemption, certain aspects of these transactions might be prohibited by section 406 of the Employee Retirement Income Security Act (ERISA).

The information collection requirements incorporated within this class exemption are intended to protect the interests of plan participants and beneficiaries and provide the Department with sufficient information to support a finding that the exemption meets the statutory standards of section 406 of ERISA.

Agency: Employee Benefits Security Administration.

Type of Review: Extension of currently approved collection.

Title: Prohibited Transaction Class Exemption 96–62; Process for Expedited Approval of an Exemption for Prohibited Transaction.

OMB Number: 1210–0098.

Frequency: On occasion.

Type of Response: Reporting and third party disclosure.

Affected Public: Business or other for-profit; not-for-profit institutions; and individuals or households.

Number of Respondents: 45.

Number of Annual Responses: 45.

Estimated Time per Response: 1.5 minutes.

Total Burden Hours: 56.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $40,463.

Description: Prohibited Transaction Exemption 96–62, which, pursuant to the exemption procedure set forth in 29 CFR part 2570, subpart B, permits a plan to seek approval on an accelerated basis of other wise prohibited transactions. The information collection requirements of this class exemption provide the Department with sufficient information to support a finding that the exemption meets the statutory standards of section 408(a) of Employee Retirement Income Security Act of 1974.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–2195 Filed 2–3–05; 8:45 am]

BILLING CODE 4510–29–M

DEPARTMENT OF LABOR

Employment Standards Administration; Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act ow March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of

submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of the decisions listed to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Maine
ME030001 (Jun. 13, 2003)
ME030002 (Jun. 13, 2003)
ME030008 (Jun. 13, 2003)
Rhode Island
RI030001 (Jun. 13, 2003)
Vermont
VT030001 (Jun. 13, 2003)
VT030011 (Jun. 13, 2003)

Volume II

Delaware
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DE030004 (Jun. 13, 2003)
DE030005 (Jun. 13, 2003)
DE030006 (Jun. 13, 2003)
DE030007 (Jun. 13, 2003)
DE030009 (Jun. 13, 2003)
DE030010 (Jun. 13, 2003)
DE030011 (Jun. 13, 2003)

Volume III

Alabama
AL030003 (Jun. 13, 2003)
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AL030008 (Jun. 13, 2003)
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AL030033 (Jun. 13, 2003)
Kentucky
KY030001 (Jun. 13, 2003)
KY030002 (Jun. 13, 2003)
KY030003 (Jun. 13, 2003)
KY030004 (Jun. 13, 2003)
KY030005 (Jun. 13, 2003)
KY030006 (Jun. 13, 2003)
KY030007 (Jun. 13, 2003)
KY030029 (Jun. 13, 2003)
KY030032 (Jun. 13, 2003)
KY030035 (Jun. 13, 2003)
KY030039 (Jun. 13, 2003)
Mississippi
MS030001 (Jun. 13, 2003)
MS030003 (Jun. 13, 2003)
MS030031 (Jun. 13, 2003)

Volume IV

Illinois
IL030001 (Jun. 13, 2003)
IL030002 (Jun. 13, 2003)
IL030003 (Jun. 13, 2003)
IL030004 (Jun. 13, 2003)
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IL030006 (Jun. 13, 2003)
IL030007 (Jun. 13, 2003)
IL030008 (Jun. 13, 2003)
IL030009 (Jun. 13, 2003)
Indiana
IN030001 (Jun. 13, 2003)
IN030002 (Jun. 13, 2003)
IN030003 (Jun. 13, 2003)
IN030004 (Jun. 13, 2003)
IN030005 (Jun. 13, 2003)
IN030006 (Jun. 13, 2003)
IN030008 (Jun. 13, 2003)
IN030009 (Jun. 13, 2003)
IN030010 (Jun. 13, 2003)
IN030011 (Jun. 13, 2003)
IN030012 (Jun. 13, 2003)
IN030014 (Jun. 13, 2003)
IN030019 (Jun. 13, 2003)
IN030020 (Jun. 13, 2003)
IN030021 (Jun. 13, 2003)
Ohio
OH030001 (Jun. 13, 2003)
OH030002 (Jun. 13, 2003)
OH030003 (Jun. 13, 2003)
OH030009 (Jun. 13, 2003)
OH030020 (Jun. 13, 2003)
OH030023 (Jun. 13, 2003)
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OH030027 (Jun. 13, 2003)
OH030029 (Jun. 13, 2003)
OH030032 (Jun. 13, 2003)
OH030033 (Jun. 13, 2003)
OH030034 (Jun. 13, 2003)
OH030035 (Jun. 13, 2003)
OH030036 (Jun. 13, 2003)

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AR030003 (Jun. 13, 2003)
Louisiana
LA03002 (Jun. 13, 2003)
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LA03005 (Jun. 13, 2003)
LA03006 (Jun. 13, 2003)
LA03009 (Jun. 13, 2003)
LA03014 (Jun. 13, 2003)
LA03052 (Jun. 13, 2003)
New Mexico
NM030001 (Jun. 13, 2003)
NM030011 (Jun. 13, 2003)

Volume VI

Colorado
CO030001 (Jun. 13, 2003)
CO030002 (Jun. 13, 2003)
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CO030004 (Jun. 13, 2003)
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CO030009 (Jun. 13, 2003)
CO030010 (Jun. 13, 2003)
CO030011 (Jun. 13, 2003)
CO030016 (Jun. 13, 2003)
Wyoming
WY030005 (Jun. 13, 2003)

Volume VII

None

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage determinations Issued Under the Davis-Bacon And Related Acts.''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *http://www.access.gpo.gov/davisbacon*. They are also available electronically by subscription to the Davis-Bacon Online Service (*http://davisbacon.fedworld.gov*) of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help Desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate Volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC, this 27th day of January, 2005.

Terry Sullivan,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 05–1872 Filed 2–3–05; 8:45 am]

BILLING CODE 4510–27–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (05–014)]

NASA Advisory Council, Minority Business Resource Advisory Committee; Meeting.

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announce a forthcoming meeting of the NASA Advisory Council (NAC),

Minority Business Resource Advisory Committee.

DATES: Thursday, February 17, 2005, 9 a.m. to 4 p.m., and Friday, February 18, 2005, 9 a.m. to 12 Noon.

ADDRESSES: Goddard Space Flight Center, Greenbelt, MD 20771, Room: MCC, Bldg. 8.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph C. Thomas III, Office of Small and Disadvantaged Business Utilization, National Aeronautics and Space Administration, (202) 358–2088.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Review of previous meeting.
—NASA Small Business Program Overview for FY 2004.
—Impact of NASA Advisory Council reorganization.
—Current issues impacting minority businesses at NASA.
—Public comment.
—Panel discussion and review.
—Discussion of Small Business Administration proposed size standards rules.
—Upcoming NASA Events for small businesses.

Attendees will be requested to register with NASA Goddard Space Flight Center security at the Center Main Entrance, and will have to present a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide the following information no less than 3 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, phone); title/position of attendee. To expedite admittance, attendees can provide identifying information in advance by contacting Mr. Lamont Hames via email at *lhames@nasa.gov* or by telephone at 202–358–2088. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Visitors will be requested to sign a visitor's register.

Dated: January 31, 2005.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 05–2165 Filed 2–3–05; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (05–015)]

NASA International Space Station Strategic Roadmap Committee; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA International Space Station Strategic Roadmap Committee.

DATES: Wednesday, February 23, 2005, 9 a.m. to 5:30 p.m., Thursday, February 24, 2005, 9 a.m. to 2 p.m. Eastern Standard Time.

ADDRESSES: Loews Annapolis Hotel, 126 West Street, Annapolis, MD 21401.

FOR FURTHER INFORMATION CONTACT: Ms. Stacey Edgington, 202–358–4519.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the meeting room. Attendees will be requested to sign a register.

The agenda for the meeting is as follows:

—NASA Strategic Roadmap Overview.
—ISS Development and Operations Status.
—ISS Utilization Study Status.
—Biomedical Studies for Exploration.
—Technology Demonstrations for Exploration.
—Integrated Space Operations Summit.
—ISS Roadmap Committee Discussion.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Dated: January 31, 2005.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 05–2166 Filed 2–3–05; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINSTRATION

[Notice 05–013]

Return to Flight Task Group; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting by teleconference of the Return to Flight Task Group (RTF TG).

DATES: Thursday, February 17, 2005, from 11 a.m. until 12:30 p.m. Central Standard Time.

ADDRESSES: The teleconference will originate from the Apollo Annex, Suite 101, 1740 NASA Parkway, Houston, TX, 77598.

FOR FURTHER INFORMATION CONTACT: Mr. Vincent D. Watkins at (281) 792–7523.

SUPPLEMENTARY INFORMATION: The public may monitor the teleconference audio from the Apollo Annex Room 175 up to the seating capacity of the meeting room. Attendees will be requested to sign a register. Audio of the teleconference will be distributed via the Internet at *http://returntoflight.org*.

The agenda for the meeting is as follows:

—Welcome remarks from Co-Chair.
—Discussion of status of NASA's implementation of selected Columbia Accident Investigation Board return to flight recommendations.
—Action item summary from Executive Secretary.
—Closing remarks from Co-Chair.

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 05–2164 Filed 2–3–05; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

Application for a License To Export High-Enriched Uranium

Pursuant to 10 CFR 110.70(b)(2) ''Public notice of receipt of an application,'' please take notice that the Nuclear Regulatory Commission has received the following request for an export license. Copies of the request can be accessed through the Public Electronic Reading Room (PERR) link *http://www.nrc.gov/reading-rm/adams.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office

of the General Counsel, U.S. Nuclear Regulatory Commission, Washington DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

In its review of the application for a license to export special nuclear material as defined in 10 CFR Part 110 and noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recipient nation of the material to be exported. The information concerning the application follows.

NRC EXPORT LICENSE APPLICATION FOR HIGH-ENRICHED URANIUM

Name of applicant Date of application Date received Application number Docket number	Material type	End use	Country of destination
DOE/NNSA—Y12 September 7, 2004 September 24, 2004 XSNM03369 11005512	High-Enriched Uranium	To fabricate targets for irradiation in the National Research Universal (NRU) Reactor to produce medical isotopes	Canada.

For the Nuclear Regulatory Commission.

Dated this 24 day of January, 2005, at Rockville, Maryland.

Margaret M. Doane,

Deputy Director, Office of International Programs.

[FR Doc. 05–2134 Filed 2–3–05; 8:45 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–33635, License No.45–15200–04, EA–04–103]

In the Matter of Soil Consultants, Inc., ATTN: Mr. Joseph W. Dixon, President, 9303 Center Street, Manassas, VA 20110–5547; Order Imposing Civil Monetary Penalty

I

Soil Consultants, Inc. (Licensee) is the holder of Materials License No. 45–15200–04 issued by the Nuclear Regulatory Commission (NRC or Commission) on October 6, 2004, Amendment No. 03. The license authorizes the Licensee to use sealed source(s) contained in portable gauging devices (registered pursuant to 10 CFR 32.320 or equivalent Agreement State regulation) for measuring properties of materials in accordance with the conditions specified therein.

II

An investigation of the Licensee's activities was completed on February 11, 2004. The results of this investigation and the NRC's further consideration of this matter, including a predecisional enforcement conference held with you on August 12, 2004, indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated October 6, 2004. The Notice states the nature of violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation.

The licensee responded to the Notice in letters dated November 5, 2004, and December 2, 2004. In its response, the Licensee denied a violation occurred.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282 and 10 CFR 2.205, *it is herby ordered that:*

The Licensee pay a civil penalty in the amount of $9,600 within 30 days of the date of this Order, in accordance with NUREG/BR–0254. In addition, at the time of making payment, the licensee shall submit a statement indicating when, and by what method, payment was made, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738.

V

The Licensee may request a hearing within 30 days of the date of this Order. Where good cause is shown, such as requesting to engage in alternative dispute resolution, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension. A request for a hearing should be clearly marked as a ''Request for an Enforcement Hearing'' and shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Rulemaking and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, PA 19406–1415. Because of continuing disruption in delivery of mail to United States Government offices, it is requested that requests for hearings be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301–415–1101 or by e-mail to *hearingdocket@nrc.gov* and also to the Office of the General Counsel either by means of facsimile transmission to 301–415–3725 or by e-mail to *OGCMailCenter@nrc.gov*.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order (or if written approval of an extension of time in which to request a hearing has not been granted), the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event that the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the Licensee was in violation of the Commission's requirements as set forth in the Notice referred to in Section II above, and

(b) Whether, on the basis of such violation, this Order should be sustained.

Dated this 27th day of January 2005.

For the Nuclear Regulatory Commission.

Frank J. Congel,

Director, Office of Enforcement.

[FR Doc. 05–2136 Filed 2–3–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–20885]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment for Genzyme Biosurgery's Facility in Ridgefield, NJ

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

FOR FURTHER INFORMATION CONTACT: Kathy Dolce Modes, Materials Security & Industrial Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, telephone (610) 337–5251, fax (610) 337–5269; or by e-mail: *KAD@NRC.GOV*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Nuclear Regulatory Commission (NRC) is issuing a license amendment to Genzyme Biosurgery for Materials License No. 29–23308–01, to authorize release of its facility in Ridgefield, New Jersey for unrestricted use. NRC has prepared an Environmental Assessment (EA) in support of this action in accordance with the requirements of 10 CFR part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The amendment will be issued following the publication of this notice.

II. EA Summary

The purpose of the action is to authorize the release of the licensee's Ridgefield, New Jersey facility for unrestricted use. Genzyme Biosurgery was authorized by NRC from December 23, 1983, to use radioactive materials for research and development purposes at the site. On June 4, 2004, Genzyme Biosurgery requested that NRC release the facility for unrestricted use. Genzyme Biosurgery has conducted surveys of the facility and provided information to the NRC to demonstrate that the site meets the license termination criteria in subpart E of 10 CFR part 20 for unrestricted use.

The NRC staff has prepared an EA in support of the license amendment. The facility was remediated and surveyed prior to the licensee requesting the license amendment. The NRC staff has reviewed the information and final status survey submitted by Genzyme Biosurgery. Based on its review, the staff has determined that there are no additional remediation activities necessary to complete the proposed action. Therefore, the staff considered the impact of the residual radioactivity at the facility and concluded that since the residual radioactivity meets the requirements in subpart E of 10 CFR part 20, a Finding of No Significant Impact is appropriate.

III. Finding of No Significant Impact

The staff has prepared the EA (summarized above) in support of the license amendment to terminate the license and release the facility for unrestricted use. The NRC staff has evaluated Genzyme Biosurgery's request and the results of the surveys and has concluded that the completed action complies with the criteria in subpart E of 10 CFR part 20. The staff has found that the environmental impacts from the action are bounded by the impacts evaluated by NUREG–1496, Volumes 1–3, ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Facilities'' (ML042310492, ML042320379, and ML042330385). On the basis of the EA, the NRC has concluded that the environmental impacts from the action are expected to be insignificant and has determined not to prepare an environmental impact statement for the action.

IV. Further Information

Documents related to this action, including the application for the license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are: Environmental Assessment (ADAMS Accession No. ML050270048), ''Report of the Decommissioning of the Genzyme Biosurgery Research and Development Laboratories for the Purpose of Surrendering the Company's Radioactive Materials License'' included with the licensee's letter dated June 4, 2004 (ADAMS Accession No. ML041800154) and additional information dated October 15, 2004 (ADAMS Accession No. ML042990427). Please note that on October 25, 2004, the NRC terminated public access to ADAMS and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's Web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS. The NRC Public Documents Room is located at NRC Headquarters in Rockville, MD, and can be contacted at (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov*.

Dated in King of Prussia, Pennsylvania this 27th day of January, 2005.

For the Nuclear Regulatory Commission.

James P. Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I.

[FR Doc. 05–2138 Filed 2–3–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–3098]

Duke Cogema Stone and Webster's Proposed Mixed Oxide Fuel Fabrication Facility; Notice of Availability of Final Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability of final environmental impact statement.

FOR FURTHER INFORMATION CONTACT: Matthew Blevins, Senior Project Manager, Environmental and Performance Assessment Directorate, Division of Waste Management and Environmental Protection, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415–7684; e-mail: *mxb6@nrc.gov*.

SUMMARY: Notice is hereby given that the U.S. Nuclear Regulatory

Commission (NRC) is issuing a Final Environmental Impact Statement (FEIS) on the proposed construction and operation of a mixed oxide (MOX) fuel fabrication facility at the Savannah River Site in South Carolina. The FEIS is being issued as part of the NRC's decision-making process on whether to authorize Duke Cogema Stone & Webster (DCS), a contractor of the U.S. Department of Energy (DOE), to construct and operate the proposed MOX fuel fabrication facility (MOX facility).

The proposed MOX facility would convert depleted uranium dioxide and weapons-grade plutonium dioxide into MOX fuel. The FEIS discusses the purpose and need for the proposed MOX facility, and reasonable alternatives to the proposed action, including the no-action alternative. The FEIS also discusses the environment potentially affected by the proposal, presents and compares the potential environmental impacts resulting from the proposed action and its alternatives, and identifies mitigation measures that could eliminate or lessen the potential environmental impacts.

The FEIS is being issued as part of the NRC's decision-making process on whether to authorize DCS to begin construction of the proposed MOX facility. The FEIS will also be relevant to any later decision on whether to authorize DCS to operate the MOX facility. Based on the evaluation in the FEIS, the NRC environmental review staff have concluded that the proposed action will generally have small effects on the public and existing environment. This FEIS reflects the final analysis of environmental impacts of DCS's proposal and its alternatives including the consideration of public comments received by the NRC. In addition, the FEIS provides summaries of the substantive public comments on the draft EIS, and responses, as appropriate.

Several pages in the FEIS have been removed from public access based on the additional security reviews that the NRC initiated on October 25, 2004. The material on these pages is being withheld pursuant to 10 CFR 2.390(a).[1]

ADDRESSES: The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The FEIS and its appendices may be accessed through the NRC's Public Electronic Reading Room on the Internet at *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 NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov*. Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's Web site. Pending resumption of public access to ADAMS, interested members of the public may obtain copies of the referenced documents that have undergone security screening by contacting the Public Document Room at the above phone number.

The FEIS is also available for inspection at the Commission's Public Document Room, U.S. NRC's Headquarters Building, 11555 Rockville Pike (first floor), Rockville, Maryland. Upon written request and to the extent supplies are available, a single copy of the FEIS can be obtained for a fee by writing to the Office of the Chief Information Officer, Reproduction and Distribution Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; by electronic mail at *DISTRIBUTION@nrc.gov*; or by fax at (301) 415–2289.

A selected group of documents associated with the MOX facility may also be obtained from the Internet on NRC's MOX facility Web page: *http://www.nrc.gov/materials/fuel-cycle-fac/mox/licensing.html* (case sensitive).

SUPPLEMENTARY INFORMATION: In January 2000, the DOE issued a Record of Decision pertaining to its surplus plutonium disposition program and the DOE's 1999 EIS related to this program (65 FR 1608). The fundamental purpose of the DOE program is to ensure that plutonium produced for nuclear weapons and declared excess to national security needs is converted to forms that are inaccessible and unattractive for use in nuclear weapons.

The FEIS for the proposed MOX facility was prepared by the staff of the NRC and its contractor, Argonnne National Laboratory, in compliance with the National Environmental Policy Act (NEPA), and the NRC's regulations for implementing NEPA (10 CFR part 51). The proposed action involves a decision by NRC of whether to authorize DCS to construct and later operate the proposed MOX facility at the Savannah River Site to convert surplus weapons plutonium into MOX fuel.

If approved by the NRC, the proposed MOX facility would be built in the F-Area of the DOE's Savannah River Site (SRS). Feedstock (surplus plutonium dioxide and depleted uranium dioxide) would have to be transported to SRS to make the MOX fuel. To support operation of the proposed MOX facility, two other new facilities would have to be built by the DOE at the SRS. Infrastructure upgrades, such as construction waste transfer pipelines, electric utility line realignment, and addition of access roads, would also be required. Any MOX fuel made at the proposed MOX facility would be transported to mission reactors, where it would be irradiated.

The NRC published a Notice of Intent to prepare an Environmental Impact Statement for the proposed MOX facility, and to conduct a scoping process, in the **Federal Register** on March 7, 2001 (66 FR 13794). NRC staff subsequently held scoping meetings, and issued a Scoping Summary Report in August 2001. In April 2002, DOE issued an amended Record of Decision changing its planned approach for surplus weapons plutonium disposition (67 FR 19432). On August 22, 2002, the NRC announced public meetings to discuss changes in DCS Environmental Report (ER) that resulted from changes in DOE's plans (67 FR 54501). The meetings were held on September 17, 2002, in Savannah, Georgia, September 18, 2002, in Augusta, Georgia, and September 19, 2002, in Charlotte, North Carolina. On June 20, 2003, DCS submitted Revision 3 of its ER, and on August 13, 2003, DCS submitted Revision 4 of its ER, and on June 10, 2004, DCS submitted Revision 5 of its ER. These revisions are summarized in Appendix J of the FEIS.

The FEIS describes the proposed action, and alternatives to the proposed action, including the no-action alternative. The FEIS discussion of the no-action alternative evaluates the environmental impacts of the continued storage of surplus plutonium in various DOE locations nationwide, in the event NRC decides not to approve the proposed MOX facility. Alternatives considered but not analyzed in detail include alternate locations for the proposed MOX facility in the F-Area, alternative technology and design options, immobilization of surplus plutonium instead of producing MOX fuel, deliberately making off-specification MOX fuel, and the Parallex Project, the latter of which involves irradiating the MOX fuel in Canadian Deuterium-Natural Uranium Reactors. Additionally, the FEIS compares the impacts of using high-efficiency

[1] Please note that the MOX proceeding is governed by the old 10 CFR Part 2 provisions. Under the old regulation, the material being withheld is in accordance with 10 CFR 2.790(a).

particulate air filters to the impacts of using sand filters for removal of particulate air emissions.

After weighing the impacts, costs, and benefits of the proposed action and comparing alternatives (*see* Chapter 4 of the FEIS), the NRC staff, in accordance with 10 CFR 51.91(d), sets forth its final NEPA recommendation regarding the proposed action. The NRC staff recommends that, unless safety issues mandate otherwise, the action called for is the issuance of the proposed license to DCS with conditions to protect environmental values.

The NRC staff in the Division of Fuel Cycle Safety and Safeguards are currently completing the safety review of DCS' construction authorization request. The final decision is currently scheduled for the Spring of 2005.

Dated in Rockville, Maryland, this 21st day of December, 2004.

For the Nuclear Regulatory Commission.

Scott C. Flanders,

Deputy Director, Environmental and Performance Assessment Directorate, Division of Waste Management and Environmental Protection, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 05–2137 Filed 2–3–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Nuclear Waste; Meeting on Planning and Procedures; Notice of Meeting

The Advisory Committee on Nuclear Waste (ACNW) will hold a Planning and Procedures meeting on February 23, 2005, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACNW, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, February 23, 2005—8:30 a.m.–10 a.m.

The Committee will discuss proposed ACNW activities and related matters. The purpose of this meeting is to gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official, Mr. Michael P. Lee (Telephone: (301) 415–6887) between 7:30 a.m. and 4:15 p.m. (e.t.) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public.

Further information regarding this meeting can be obtained by contacting the Designated Federal Official between 7:30 a.m. and 4:15 p.m. (e.t.). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes in the agenda.

Dated: January 27, 2005.

John H. Flack,

Acting Branch Chief, ACRS/ACNW.

[FR Doc. 05–2135 Filed 2–3–05; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

Grants Related Information Collections Under OMB Review

AGENCY: Office of Management and Budget.

ACTION: Notice of submission for OMB review, comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*), this notice announces that eight information collection renewal requests were submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) for processing under 5 CFR 1320.10. The first notice of these information collection renewals was published in the **Federal Register**, as required by the Paperwork Reduction Act, on October 29, 2004 [69 FR 63186], and invited the general public and Federal agencies to comment on the renewal without change of eight (8) standard forms: the SF–269, Financial Status Report (long form); SF–269A, Financial Status Report (short form); SF–272, Federal Cash Transactions Report; SF–272A, Federal Cash Transactions Report (continuation); SF–424A, Budget Information—Nonconstruction Programs; SF–424B, Assurances—Non-construction Programs; SF–424C, Budget Information—Construction Programs; and SF–424D, Assurances—Construction Programs. These forms are currently required by OMB Circular A–102, ''Grants and Cooperative Agreements with State and Local Governments,'' and Title 2 Code of Federal Regulations Part 215 (OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.'' These eight forms will continue to be used while interagency teams working under two streamlining initiatives (the Grants.gov E-Gov effort and the P.L.106–107 implementation work groups) complete the final consolidated data standards.

DATES: Comments must be submitted on or before March 7, 2005. Late comments will be considered to the extent practicable.

ADDRESSES: Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic mail comments may be submitted to: *ahunt@omb.eop.gov.* Please include ''Grant Forms'' in the subject line and place the full body of your comments in the text of the electronic message (and as an attachment if you wish). Please include your name, title, organization, postal address, telephone number, and E-mail address in the text of the message. Comments may also be submitted via Facsimile to 202–395–7285. Comments may be mailed to Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10236, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Elizabeth Phillips, Office of Federal Financial Management, Office of Management and Budget, (202) 395–3993. The standard forms can be downloaded from the OMB Grants Management home page (*http://www.whitehouse.gov/omb/grants*) by selecting the ''Forms'' option.

SUPPLEMENTARY INFORMATION:

A. Background

OMB Control No.: 0348–0039.

Title: Financial Status Report (Long Form).

Form No.: SF–269.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 100,000.

Estimated Time Per Response: 60 minutes.

Needs and Uses: The SF–269 is used to report on outlays, including use of any earned program income and matching funds contributed by the grantee. The Federal awarding agencies and OMB use information reported on this form for general management of Federal assistance program awards.

OMB Control No.: 0348–0038.

Title: Financial Status Report (Short Form).

Form No.: SF–269A.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 50,000.

Estimated Time Per Response: 40 minutes.

Needs and Uses: The SF–269A is used to report on outlays, including use of any earned program income and matching funds contributed by the grantee. The Federal awarding agencies and OMB use information reported on this form for general management of Federal assistance program awards.

OMB Control No.: 0348–0003.

Title: Federal Cash Transactions Report.

Form No.: SF–272.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 50,000.

Estimated Time Per Response: 40 minutes.

Needs and Uses: The SF–272 is used to report on cash received. The Federal awarding agencies and OMB use information reported on this form for general management of Federal assistance program awards.

OMB Control No.: 0348–0003.

Title: Federal Cash Transactions Report (continuation).

Form No.: SF–272A.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 25,000.

Estimated Time Per Response: 40 minutes.

Needs and Uses: The SF–272A is used to report on cash received. The Federal awarding agencies and OMB use information reported on this form for general management of Federal assistance program awards.

OMB Control No.: 0348–0044.

Title: Budget Information—Non-Construction.

Form No.: SF–424A.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 100,000.

Estimated Time Per Response: 60 minutes.

Needs and Uses: The SF–424A is used to provide budget information when applying for non-construction Federal grants. The Federal awarding agencies use information reported on this form for the award and general management of Federal assistance program awards.

OMB Control No.: 0348–0040.

Title: Assurances—Non-construction Programs.

Form No.: SF–424B.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 100,000.

Estimated Time Per Response: 10 minutes.

Needs and Uses: The SF–424B is used to provide information on required assurances when applying for non-construction Federal grants. The Federal awarding agencies use information reported on this form for the award and general management of Federal assistance program awards.

OMB Control No.: 0348–0041.

Title: Budget Information—Construction Programs.

Form No.: SF–424C.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 40,000.

Estimated Time Per Response: 60 minutes.

Needs and Uses: The SF–424C is used to provide budget information when applying for Federal construction grants. The Federal awarding agencies use information reported on this form for the award and general management of Federal assistance program awards.

OMB Control No.: 0348–0042.

Title: Assurances—Construction Programs.

Form No.: SF–424D.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 40,000.

Estimated Time Per Response: 10 minutes.

Needs and Uses: The SF–424D is used to provide information on required assurances when applying for Federal construction grants. The Federal awarding agencies use information reported on this form for the award and general management of Federal assistance program awards.

B. Public Comments and Responses

Pursuant to the October 29, 2004, **Federal Register** notice, OMB received two comment letters relating to the proposed information collection renewals. One commentor noted the ''Needs and Uses'' statements for the SF–269 and SF–269A was incorrect. We agree, and have corrected those statements in this notice. The other comment from a State government agency related exclusively to the SF–424 form not being posted in a ''fill-enabled and electronically saveable'' format. We encourage use of the electronic application process under Grants.gov (*http://www.grants.gov*) where the SF–424 is fill-enabled and electronically saveable. The form posted on OMB's website is available in read-only ''pdf'' format.

David Zavada,

Chief, Financial Standards and Grants Branch.

[FR Doc. 05–2103 Filed 2–3–05; 8:45 am]

BILLING CODE 3110–01–P

OFFICE OF MANAGEMENT AND BUDGET

Grants Related Information Collection Under OMB Review

AGENCY: Office of Management and Budget.

ACTION: Notice of submission for OMB review, comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*), this notice announces that an information collection extension request was submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) for processing under 5 CFR 1320.10. The first notice of this information collection extension was published in the **Federal Register** as required by the Paperwork Reduction Act, on October 29, 2004 [69 FR 63186] and invitee the general public and Federal agencies to comment on the extension without change of standard form, SF–424, Application for Federal Assistance. This form is currently required by OMB Circular A–102, ''Grants and Cooperative Agreements with State and Local Governments,'' and Title 2 Code of Federal Regulations Part 215 (OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.'' The form will continue to be used while the E-GOV Grants.gov interagency team completes their analysis of public comments received in response to an April 8, 2003, **Federal Register** notice

[68 FR 17090] and finalizes the government-wide data standard.

DATES: Comments must be submitted on or before March 7, 2005. Late comments will be considered to the extent practicable.

ADDRESSES: Due to potential delays in OMB's receipt and processing of mail sent through the U. S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic mail comments may be submitted to: *ahunt@omb.eop.gov*. Please include ''SF–424'' in the subject line and the full body of your comments in the text of the electronic message (and as an attachment if you wish). Please include your name, title, organization, postal address, telephone number, and E-mail address in the text of the message. Comments may also be submitted via facsimile to 202–395–7285. Comments may be mailed to Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10236, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Elizabeth Phillips, Office of Federal Financial Management, Office of Management and Budget, (202) 395–3993. The standard forms can be downloaded from the OMB Grants Management home page (*http://www.whitehouse.gov/omb/grants*).

SUPPLEMENTARY INFORMATION

A. Background

OMB Control No.: 0348–0043.

Title: Application for Federal Assistance.

Form No.: SF–424.

Type of Review: Extension of a currently approved collection.

Respondents: States, Local Governments, non-profit organizations.

Number of Responses: 100,000.

Estimated Time Per Response: 20 minutes.

Needs and Uses: The SF–424 is used to provide general information about the entity and the proposed project when applying for Federal assistance under grant and cooperative agreement awards. The Federal awarding agencies use information reported on this form for the pre-award and award processes.

B. Public Comments and Responses

Pursuant to the October 29, 2004, **Federal Register** notice, OMB received one comment letter relating to the proposed SF–424 information collection extension. The comment from a State government agency noted that the SF–424 was not posted in a ''fill-enabled and electronically saveable'' format. We encourage use of the electronic application process under Grants.gov (*http://www.grants.gov*) where the SF–424 is fill-enabled and electronically saveable. The form posted on OMB's website is available in read-only ''pdf'' format.

David Zavada,

Chief, Financial Standards and Grants Branch.

[FR Doc. 05–2104 Filed 2–3–05; 8:45 am]

BILLING CODE 3110–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Mosaic Nutriceuticals Corp.; Order of Suspension of Trading

February 2, 2005.

It appears to the Securities and Exchange Commission that the public interest and the protection of investors require a suspension of trading in the securities of Mosaic Nutriceuticals Corp. (''Mosaic''). The Commission is concerned that Mosaic and/or certain of its shareholders may have unjustifiably relied on Rule 144(k) of the Securities Act of 1933 (''Securities Act'') in conducting an unlawful distribution of its securities that failed to comply with the resale restrictions of Rules 144 and 145 of the Securities Act. Mosaic, a company that has made no public filings with the Commission or the NASD, is quoted on the Pink Sheets under the ticker symbol MCNJ, and has been the subject of a spam e-mail touting the company's shares.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the above listed company is suspended for the period from 9:30 a.m. e.s.t. February 2, 2005 through 11:59 p.m. e.s.t., on February 15, 2005.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 05–2264 Filed 2–2–05; 1:19 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51107; File No. SR–CBOE–2004–75]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendments No. 1 and 2 Thereto by the Chicago Board Options Exchange, Incorporated Relating to the Introduction of Remote Market-Makers

January 31, 2005.

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 November 22, 2004, 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 prepared by CBOE. On January 10, 2005, CBOE filed Amendment No. 1 to the proposed rule change.[3] On January 21, 2005, CBOE filed Amendment No. 2 to the proposed rule change.[4] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE proposes to adopt rules authorizing remote market making. The text of the proposed rule change is available on the CBOE's Web site (*http://www.cboe.com*), at the CBOE's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 replaces and supercedes CBOE's original 19b–4 filing in its entirety.

[4] Amendment No. 2 replaces and supercedes CBOE's original 19b–4 filing and Amendment No. 1 in their entirety.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

CBOE's Hybrid Trading System merges the electronic and open outcry trading models, offering market participants the ability to stream electronically their own firm disseminated market quotes representing their trading interest. The current Hybrid rules allow Market-Makers (''Market-Maker'' or ''MMs'' or ''market maker'') to stream electronic quotes only when they are physically present in their appointed trading stations. This requirement prevents ''remote market making,'' a practice whereby Market-Makers may submit quotes from locations outside of the physical trading station for that class.

CBOE proposes to adopt rules accommodating remote market making. To this end, CBOE proposes to authorize a new membership status called Remote Market-Maker (''RMM''). RMMs would have the ability to submit quotes to the CBOE from a location outside of the physical trading station for the subject class. To accommodate RMMs, the Exchange proposes to amend existing, and adopt new, rules addressing RMM obligations, RMM appointments, Priority and Allocation of Trades, and Evaluation of RMMs, as described below.

CBOE Rule 8.1 Market-Maker Defined

The Exchange proposes to amend CBOE Rule 8.1 to eliminate from the definition of Market-Maker the requirement that transactions be effected on the trading floor. Transactions by market makers that comply with the requirements of CBOE Rule 8.7.03 would be considered market maker transactions.[5] The Exchange also proposes to clarify that the term market maker includes an RMM.

CBOE Rule 8.3 Appointment of Market-Makers

The Exchange proposes to amend CBOE Rule 8.3 to clarify its non-applicability to RMMs.

CBOE Rule 8.4 RMMs

The Exchange proposes to adopt new CBOE Rule 8.4 to address the definitional, registration, affiliation, and appointment issues relating to RMMs. Proposed CBOE Rule 8.4(a) defines an RMM as an individual member or member organization registered with the Exchange that makes transactions as a dealer-specialist from a location other than the physical trading station for the subject class. The rule also proposes that transactions of RMMs that are executed on the Exchange are deemed MM transactions for purposes of Chapter VIII of the CBOE Rules and CBOE Rules 3.1 and 12.3(f).

Proposed paragraph (b), Registration and Approval of RMMs, provides that the registration and approval of RMMs would be in accordance with CBOE Rule 8.2.[6] As a result, RMMs would be approved in the same manner that MMs are approved and any member approved as a MM would be approved as an RMM upon requesting RMM status with the Exchange's Membership department. An RMM retains its approval to act as an RMM until the RMM requests the Exchange to relieve it of its approval to act as an RMM and the Exchange grants such approval or until the Exchange terminates its approval to act as an RMM pursuant to Exchange Rules.[7] Proposed paragraph (b) also states that an RMM may not transfer its approval to act as an RMM unless approved by the Exchange.

Proposed paragraph (c) governs affiliation limitations and provides that except as provided in subparagraphs (i) and (ii), an RMM may not have an appointment as an RMM in any class in which it or its member organization serves as Designated Primary Market-Maker (''DPM''), electronic DPM (''e-DPM''), RMM, or MM on CBOE. Subparagraph (i) proposes an exception to allow a CBOE Member or Member Firm operating as an RMM in a class to have, as part of an 18-month pilot program, one MM affiliated with the RMM organization trading in open outcry in any specific option class allocated to the RMM, provided such market maker trades on a separate membership.[8] This is identical to the e-DPM pilot program in which an e-DPM also may have an affiliated MM in the same class.[9]

Subparagraph (ii) proposes an exception to allow a CBOE Member or Member Firm to have, as part of a 12-month pilot program, multiple aggregation units operating as separate RMMs within the same class provided specific criteria are satisfied. CBOE believes there to be three primary instances in which this proposed multiple aggregation unit exception would be utilized. For example, large broker-dealers (''BDs'') are divided into desks that pursue separate trading strategies, and each of these trading desks may be interested in serving in an RMM capacity. Without an aggregation unit exception, each BD would be limited to only one RMM, regardless of the number of trading desks it employs and regardless of the degree of autonomy or separation between each desk.

Second, a common organizational structure utilized by CBOE MMs involves a common financial backer providing capital to multiple independent, unaffiliated MMs. Each of these MMs trades independently and has its own profit-loss account that is separate and distinct from that of the other MMs receiving financial backing from the same entity. Without an aggregation unit exception, these independent MMs could be viewed as affiliated and thus be precluded from being RMMs in the same classes. Third, given the rapidly escalating costs of acquiring sophisticated quoting technology, many MMs, in an effort to reduce their operating costs, have pooled resources to acquire such technology. Despite the shared expenses and pooled resources, these MMs continue to operate independently with their own separate profit-loss accounts, which are unaffected by the profitability (or lack thereof) of others with whom they have shared costs/pooled resources. Without the ability for each MM to be treated as an aggregation unit, these MMs would be precluded from trading as RMMs within the same classes.

In this regard, CBOE proposes to allow multiple aggregation units to operate as RMMs in the same class provided they comply with the following criteria.[10]

(A) The member or member firm has a written plan of organization that identifies each aggregation unit, specifies its trading objective(s), and supports its independent identity. The independence of aggregation units may

[5] CBOE Rule 8.7.03 is discussed in greater detail below.

[6] The Exchange proposes a corresponding change to CBOE Rule 8.2(a) to provide that applicants must pass a member's exam as opposed to a floor member's exam.

[7] The termination of an RMM's approval to act as an RMM would be pursuant to proposed CBOE Rules 8.61 or 8.4(e).

[8] As part of the pilot program, CBOE represents that it would confidentially provide the Commission with data on (1) the size of orders that RMMs and affiliated MMs both trade with electronically; (2) the price and size of the RMM's and the affiliated MM's respective quotes; (3) the price and size of quotes of other participants in classes where an RMM and an affiliate are quoting; and, (4) a breakdown of how orders are allocated to the RMM, the affiliated MM, and any other participants.

[9] *See* CBOE Rule 8.93(vii).

[10] These criteria are based on the criteria contained in Regulation SHO, which was recently adopted by the Commission. Securities Exchange Act Release No. 50103 (July 28, 2004), 69 FR 48008 (August 6, 2004) (File No. S7–23–03).

be evidenced by separate management structures, location, business purpose, or separate profit-and-loss treatment within the member firm. Each aggregation unit must maintain all trading activity of that aggregation unit in a segregated account, which would be reported to the Exchange as such.

(B) Each aggregation unit must operate independently of other aggregation units of the member or member firm. Moreover, all traders in an aggregation unit may pursue only the trading objectives or strategy(ies) of that aggregation unit and may not transmit or otherwise share information relating to those trading objectives or strategies to the member's or member firm's other aggregation units. The member or member firm may have risk management personnel outside of the RMM aggregation units view the positions of the multiple RMMs within the entity and direct position adjustments for risk management purposes. However, such persons may not transmit information to traders in an RMM aggregation unit about the trading strategies, objectives, or positions of another RMM aggregation unit.

Senior risk management personnel are prohibited from engaging in any of the following activities with respect to the Aggregation Units for which they oversee: (i) Establishing quoting parameters for any trader including but not limited to delta and volatility values; (ii) directing the submission of specific quotes by any trader; or (iii) directing the timing of a trader's trading activities with anything other than general, nonspecific timeframes. Prior to being approved in an RMM capacity, each member or member organization operating multiple Aggregation Units would be required to certify that it is aware of these prohibitions, that it would comply with these prohibitions, and that it would ensure continued compliance with these prohibitions.

(C) Individual traders are assigned to only one aggregation unit at any time; and

(D) The member or member firm as part of its compliance and/or internal audit routines establishes and maintains surveillance and audit procedures that facilitate the review and surveillance programs of the firm and CBOE to ensure the independent operation of the separate aggregation units operating as RMMs. As part of these routines, the member or member firm must retain written records of information concerning the aggregation units, including, but not limited to, trading personnel, names of personnel making trading decisions, unusual trading activities, disciplinary action resulting from a breach of the member or member firm's systems firewalls and information-sharing policies, and the transfer of securities between the members or member firm's aggregation units, which information would be promptly made available to the Exchange upon its request. The member or member firm must promptly provide to the Exchange a written report at such time there is any material change with respect to the aggregation units, at which point the Exchange would reexamine its status.

Proposed paragraph (d) governs the RMM appointment process and provides that an RMM may choose either a Physical Trading Crowd (''PTC'') or Virtual Trading Crowd (''VTC'') appointment, as described below. The proposed rule change, as amended, includes a restriction to prevent members from using a membership for multiple purposes. In this respect, proposed CBOE Rule 8.4(d) provides that memberships used to satisfy membership requirements to possess an RMM PTC or VTC appointment may not be used for any other purpose while being used in an RMM capacity, including being leased to another member or for trading on the trading floor.[11]

A PTC Appointment would correspond to the location of a physical trading station on the floor of the CBOE. An RMM that chooses a PTC appointment would have the right to quote electronically (and not in open outcry): 30 Hybrid 2.0 Platform (''Hybrid 2.0'' or ''Hybrid 2.0 Platform'') products traded in that specific trading station for each Exchange membership it owns;[12] or 20 Hybrid 2.0 products traded in that specific trading station for each Exchange membership it leases.[13]

As proposed, a VTC Appointment confers the right to quote electronically (and not in open outcry) an appropriate number of products selected from ''tiers'' that have been structured according to trading volume statistics. By being able to choose the products it wishes to trade, an RMM would have unparalleled flexibility in choosing and structuring its appointment. As proposed, RMMs would be able to choose from all products included in the Hybrid 2.0 Platform. Of those products, Tier A would consist of the 20% most actively-traded products over the preceding three calendar months, Tier B the next 20%, etc., through Tier E, which would consist of the 20% least actively-traded products. All products within a specific Tier would be assigned an ''appointment cost'' depending upon its Tier location. Each Tier A product would have an ''appointment cost'' of .10, each Tier B product would be .0667, each Tier C product would be .05, each Tier D product would be .04, and each Tier E product would be .033. An RMM as part of its VTC appointment may select for each membership it owns or leases any combination of Hybrid 2.0 products whose aggregate ''appointment cost'' does not exceed 1.0. For example, an RMM could request six ''A Tier'' products (6x.10), four ''C Tier'' products (4x.05), and five ''D Tier'' products (5x.04) to constitute its VTC appointment.

The Exchange would rebalance the ''tiers'' once each calendar quarter, which may result in additions or deletions to their composition. When a product changes ''tiers'' it would be assigned the ''appointment cost'' of that tier. Upon rebalancing, each RMM with a VTC appointment would be required to own or lease the appropriate number of Exchange memberships reflecting the revised ''appointment costs'' of the products constituting its appointment. Proposed paragraph (d) also provides that an RMM may only change its appointment upon providing advance notification to the Exchange in a form and manner prescribed by the Exchange.

Proposed paragraph (e) provides that the Exchange may suspend or terminate any appointment of an RMM in one or more classes under this rule whenever, in the Exchange's judgment, the interests of a fair and orderly market are best served by such action. This is similar to ISE Rule 802 and CBOE Rule 8.3. An RMM may seek review of any action taken by the Exchange pursuant to CBOE Rule 8.4 in accordance with Chapter XIX of the CBOE Rules.

Proposed CBOE Rule 8.4(f) provides that RMMs are subject to CBOE Rule 8.7.03A with respect to trading in appointed classes.[14] RMMs may not enter quotations in option classes that are not included within their appointments although they may submit orders in non-appointed classes.

[11] An Exchange membership includes a transferable regular membership or a Chicago Board of Trade full membership that has effectively been exercised pursuant to Article Fifth(b) of the Certificate of Incorporation.

[12] The Exchange proposes in CBOE Rule 1.1(aaa) definitions for Hybrid Trading System and Hybrid 2.0 Platform.

[13] For purposes of this rule, the term ''product'' refers to all options of the same single underlying security/value.

[14] CBOE Rule 8.7.03A requires at least 75% of a Market-Maker's total contract volume (measured quarterly) be in his/her appointed classes.

CBOE Rule 8.3A Maximum Number of Market Participants Quoting Electronically Per Product

The Exchange does not have unlimited systems bandwidth capacity to support an unlimited number of electronic quoters in every class. For this reason, the Exchange proposes to limit the number of members quoting electronically in each product (''Class Quoting Limit'' or ''CQL'') traded on Hybrid or Hybrid 2.0.[15] By limiting the number of quoters in all Hybrid and Hybrid 2.0 classes/products, the Exchange ensures it would have the ability to effectively handle all quotes generated by members. The number of members permitted to quote in each product is specified in proposed CBOE Rule 8.3A.01. The methodology for determining which members would be able to quote electronically in a product is governed by proposed CBOE Rule 8.3A(a)–(c).

When a CQL is established for each product, the following criteria govern which members are entitled to quote electronically in that subject product. A Market-Maker (excluding an RMM and e-DPM) that is not eligible to quote electronically in a product still may quote in open outcry in that product.

Products Trading on the Hybrid 2.0 Platform as of January 6, 2005 and Products Trading on the Hybrid Trading System as of January 6, 2005

The DPM and e-DPMs (if applicable [16]) assigned to the product on January 6, 2005, and MMs who: (1) Are in good standing with the Exchange; and (2)(i) have transacted at least 80% of their Market-Maker contracts and transactions in-person in each of the three immediately preceding calendar months prior to January 6, 2005 in option products traded in the trading station; or (ii) were physically present in the trading station acting in the capacity of a MM on January 6, 2005, would be entitled to quote electronically in those products for as long as they maintain an appointment in those products.[17]

All other MMs, RMMs, and approved e-DPMs that request the ability to submit quotes electronically in the subject product would be entitled to quote electronically in that product in the order in which they so request provided the number of members quoting electronically in the product does not exceed the CQL. When the number of members in the product quoting electronically equals the CQL, all other members requesting the ability to quote electronically in that product would be wait-listed in the order in which they submitted the request.

The waiting list would operate based on time priority. When the product can accommodate another electronic quoter (whether due to attrition or an increase in the CQL), the member at the ''top'' of the list (*i.e.*, the member that has been on the waiting list the longest amount of time) would have priority. Once a member is wait-listed, the Exchange may not alter his/her position on the wait-list other than to improve such position (*i.e.*, the Exchange may not place other members ahead of a previously wait-listed member). If a wait-listed member is offered, yet refuses, the ability to quote electronically in the subject product, the member would be removed from that waiting list.

Products Added to the Hybrid 2.0 Platform After January 6, 2005

With respect to a product that is added to the Hybrid 2.0 Platform after January 6, 2005, the DPM and e-DPMs appointed to the product would be entitled to quote electronically. All MMs quoting in the product prior to its addition to the Hybrid 2.0 Platform would be entitled to quote electronically provided that: (i) They have transacted at least 80% of their MM contracts and transactions in-person in each of the three immediately preceding calendar months prior to the product being added to the Hybrid 2.0 Platform in option products traded in the trading station; or (ii) they were physically present in the trading station acting in the capacity of a MM on the day prior to the product being added to the Hybrid 2.0 Platform. These standards, which also are contained in paragraph (a) of this rule, would ensure that MMs that maintained a presence in the class prior to its conversion to the Hybrid 2.0 Platform would be guaranteed the ability to quote electronically upon conversion to Hybrid 2.0. If at the time a product is added to the Hybrid 2.0 Platform the aggregate number of DPMs, e-DPMs, and MMs entitled to quote electronically in the product exceeds the CQL, then the product would have an ''increased CQL,'' as described in proposed Interpretations and Policies .01(a). Reduction of any ''increased CQL'' would be in accordance with the procedures described in proposed Interpretations and Policies .01(a).

All other members would be entitled to quote electronically in that product in the order in which they so request provided the number of members quoting electronically in the product does not exceed the CQL. When the number of members quoting electronically in the product equals the CQL, all other members would be wait-listed in the order in which they request the ability to quote electronically. The wait-list would operate as described in proposed CBOE Rule 8.3A(a).

Products Added to the Hybrid Trading System After January 6, 2005

With respect to a new product that commences trading on the Hybrid Trading System after January 6, 2005, the assigned DPM would be entitled to quote electronically. Thereafter, all other members would be entitled to quote electronically in that product in the order in which they so request provided the number of members quoting electronically does not exceed the CQL. When the number of members quoting electronically in the product equals the CQL, all other members would be wait-listed in the order in which they request the ability to quote electronically. The wait-list would operate as described in proposed CBOE Rule 8.3A(a).

Establishing the Class Quoting Limits (Proposed Interpretations and Policies .01)

There would not be a uniform CQL for each class traded on the Exchange, rather the CQL would vary by product. The section below describes the process for affixing CQLs for all products.

Products Trading on the Exchange as of January 6, 2005

CBOE proposes that the CQL for all products trading on the Hybrid Trading System would be twenty-five (25). The twenty-sixth member to request the ability to quote electronically in a Hybrid class would be first on the wait-list for that product.

The CQLs for products trading on the Hybrid 2.0 Platform would vary based on trading volume over the preceding calendar quarter. CBOE proposes that the CQL would be as follows: 40 for the 20% most actively-traded products over the preceding quarter; 35 for the next 20% most actively-traded products; 30 for the next 20% most actively-traded products; and 25 for all other Hybrid 2.0 Platform products.[18] The Exchange has selected these levels because they strike

[15] For purposes of this rule, the term ''product'' refers to all options of the same single underlying security/value.

[16] Non-Hybrid 2.0 classes do not have e-DPMs.

[17] CBOE represents that the practical effect of this rule is to ensure that the DPM, all MMs, and all e-DPMs would be guaranteed the ability to quote electronically in products trading at their primary trading stations as of January 6, 2005. CBOE further represents that there were no products as of this date for which the number of members quoting electronically exceeded the CQL for that product.

[18] *See* proposed CBOE Rule 8.3A.01.

the optimum balance between the Exchange's need to not exceed its internal quote capacity by allowing an unlimited number of quoters in every class and the need to provide greater liquidity in the more actively-traded classes.

At the end of each calendar quarter, products would be assigned a different CQL based on the revised trading volume statistics (''new CQL''). For example, if a product with 25 electronic quoters now qualifies (based on increased trading volume) for 35 electronic quoters, the CQL increases immediately and those on the wait-list would be added (if applicable). Otherwise, time priority governs who would be entitled to quote electronically in that class.

If the number of members quoting electronically in the product on the last day of the quarter equals or is less than the new CQL, then the previous CQL would be reduced immediately to the new CQL.[19] If the number of members quoting electronically in the product on the last day of the quarter is greater than the new CQL, then that product would have an ''increased'' CQL. CBOE represents that the reason for the ''increased'' CQL is to avoid having to prevent members from quoting electronically in a product in which they are already quoting. In this regard, the ''increased'' CQL would equal the number of members quoting electronically in the product on the last day of the quarter. If a member changes his/her appointment and ceases quoting electronically in that product, the ''increased'' CQL would decrease by one until such time that the number of remaining members quoting electronically in the product equals the new CQL.[20] From that point forward, the number of members quoting electronically in the product may not exceed the new CQL.

As an example, assume product ABC's existing CQL is 40, the new CQL on rebalancing date should be 30, and that 33 members are quoting electronically in the product on the last day of the quarter. Rather than prevent three members from quoting, the CQL would be increased to 33. If one of those 33 members ''drops'' the product from his/her appointment and thus no longer quotes electronically, the ''increased'' CQL would drop to 32. When two others leave, the CQL would become 30 and the first member on the wait-list would be entitled to quote electronically when one other member leaves the product.

Products Not Traded on the Exchange as of January 6, 2005

The CQL for all products newly-listed on the Exchange after January 6, 2005 would be 25 until such time that the CQL increases in accordance with this proposed Interpretations and Policies .01. In this regard, when the product's trading volume increases such that the product then qualifies for a higher CQL, it would receive a higher CQL.

Increasing the Class Quoting Limit in Exceptional Circumstances

CBOE believes that having an established upper limit on the number of members that may quote electronically in any given product works effectively for the overwhelming vast majority of products traded on CBOE. Nevertheless, there are bound to be instances in which the demand to quote in a new or existing product greatly exceeds the CQL for that product. For example, more than 150 members trade options on the S&P 500 (''SPX'') index. If the Exchange were to trade SPX options on Hybrid, a CQL of 25 would be low. It is for these rare instances that the Exchange proposes to adopt a rule to allow for a higher CQL.

In this regard, when exceptional circumstances warrant, the President of the Exchange (or in his absence his designee, who must be a Senior Vice President of the Exchange or higher) may increase the CQL for an existing or new product. ''Exceptional circumstances'' refers to substantial trading volume, whether actual or expected (*e.g.*, in the case of a new product or a major news announcement). The Exchange does not intend for this discretion (*i.e.*, to increase the CQL) to be exercised on an intra-day basis. Rather, the primary instance for which the Exchange anticipates this discretion being exercised is for the addition of new products to Hybrid or Hybrid 2.0 for where the standard CQL is not high enough to accommodate the anticipated trading volume and member demand. When the CQL increases pursuant to the President exercising his authority in accordance with this paragraph, members on the wait-list (if applicable, with respect to a product already trading on Hybrid), would have first priority and remaining capacity would be filled on a time priority basis.[21]

Upon cessation of the exceptional circumstances, the President (or his designee), in his discretion, may determine to reduce the CQL. Any reduction in the CQL must be undertaken in accordance with the procedure established in paragraph .01(a)(ii) above with respect to lowering the ''increased CQL.'' This means that if the new CQL is less than the number of members quoting electronically in that product, there would be an ''increased'' CQL. Any actions taken by the President of the Exchange pursuant to this paragraph (to increase or decrease the CQL) would be submitted to the SEC in a rule filing pursuant to Section 19(b)(3)(A) of the Act.

The Exchange would announce all changes regarding CQLs to the membership via Information Circular. The Exchange may increase the CQL levels established in paragraphs .01(a) and (b) by submitting to the SEC a rule filing pursuant to Section 19(b)(3)(A) of the Act. The Exchange may decrease the CQL levels established above upon SEC approval of a rule filing submitted pursuant to Section 19(b)(2) of the Act.

CBOE Rule 8.7 Obligations of Market-Makers

The Exchange proposes to amend CBOE Rule 8.7 to clarify the obligations applicable to RMMs. As RMMs would not be able to quote in open outcry, the Exchange proposes to amend paragraph (b)(iii) to specify the permissible methods by which in-crowd market makers and RMMs may quote or submit orders.

The Exchange also proposes to amend paragraph (d), Market Making Obligations Applicable in Hybrid Classes, to exclude RMMs from the application of this paragraph. RMMs instead would be subject to the obligations contained in new paragraph (e), which are based on the Hybrid obligations in CBOE Rule 8.7(d). Subparagraph (e)(i) states that RMMs must provide continuous two-sided, 10-up, legal-width quotations in 60% of the series of their appointed classes.[22] The Exchange may consider exceptions to this quoting requirement based on demonstrated legal or regulatory requirements or other mitigating circumstances (*e.g.*, excused leaves of

[19] *See* proposed CBOE Rule 8.3A.01(i).

[20] *See* proposed CBOE Rule 8.3A.01(ii).

[21] For new products, proposed CBOE Rule 8.3A(a)–(c) governs.

[22] If the underlying primary market disseminates a 100-share quote, an RMM's undecremented quote may be for as low as 1-contract (''1-up''), however, this ability is expressly conditioned on the process being automated (*i.e.*, an RMM may not manually adjust its quotes to reflect 1-up sizes). Quotes must automatically return to at least 10-up when the underlying primary market no longer disseminates a 100-share quote. RMMs that have not automated this process may not avail themselves of the relief provided herein. The ability to quote 1-up would operate on a pilot basis and would terminate on August 17, 2005, which is the same expiration date contained in CBOE Rules 8.7(d)(i)(B) and (d)(ii)(B) for Hybrid trading.

absence, personal emergencies, or equipment problems).[23]

Proposed subparagraph (ii) states that an RMM may be called upon by an Exchange official designated by the Board of Directors to submit a single quote or maintain continuous quotes in one or more series of an issue to which the RMM is appointed whenever, in the judgment of such official, it is necessary to do so in the interest of maintaining a fair and orderly market.[24] Proposed subparagraph (iii) provides that all Exchange rules applicable to market makers would also apply to RMMs unless otherwise provided or unless the context clearly indicates otherwise. RMMs are not considered trading crowd members except as provided in CBOE Rules 6.13 and 8.60.[25]

Proposed subparagraph (iv) provides that the evaluation of RMM performance would be pursuant to proposed CBOE Rule 8.61. Subparagraph (v) states that failure by an RMM to engage in a course of dealings as specified above would subject the RMM to disciplinary action or suspension or revocation of registration by the Exchange in one or more of the option classes in which the RMM holds an appointment.[26] Finally, proposed subparagraph (vi) requires RMMs to maintain information barriers that are reasonably designed to prevent the misuse of material, non-public information with any affiliates that may conduct a brokerage business in option classes allocated to the RMM or that may act as specialist or market maker in any security underlying options allocated to the RMM, and otherwise comply with the requirements of CBOE Rule 4.18 regarding the misuse of material non-public information.

The Exchange also proposes to amend CBOE Rule 8.7.03B regarding a MM's in-person trading percentage requirements to clarify that it has no application to RMMs (as RMMs cannot quote in person). Finally, the Exchange proposes to make CBOE Rule 8.7.09 applicable to RMMs.

CBOE Rule 8.8 Restrictions on Acting as Market-Maker and Floor Broker

The Exchange proposes to amend CBOE Rule 8.8 to eliminate the requirement that an appointment must at least include all of the classes of options traded at one station. As RMMs may customize their appointments, this requirement has no applicability.

[23] This is virtually identical to PCX Rule 6.37(h)(3).

[24] This is virtually identical to PCX Rule 6.37(h)(4).

[25] This is based on PCX Rule 6.37(h)(1) and (2).

[26] This is virtually identical to PCX Rule 6.37(h)(6).

CBOE Rule 8.61 Evaluation of RMMs

Proposed CBOE Rule 8.61 provides that the appropriate Market Performance Committee (''MPC'') would periodically conduct an evaluation of RMMs to determine whether they have fulfilled performance standards relating to, among other things, quality of markets, competition among market makers, observance of ethical standards, and administrative factors. The appropriate MPC may consider any relevant information including, but not limited to, the results of an RMM evaluation, trading data, an RMM's regulatory history and such other factors and data as may be pertinent in the circumstances.

Proposed paragraph (b) provides that the Exchange may terminate, place conditions upon, or otherwise limit a member's approval to act as an RMM on the same basis that market maker privileges may be terminated and/or conditioned under CBOE Rule 8.60. If a member's approval to act as an RMM is terminated, conditioned, or otherwise limited by the Exchange, the member may seek review of that decision under Chapter XIX of the CBOE Rules.

CBOE Rule 6.45A Priority and Allocation of Trades for CBOE Hybrid System

The Exchange proposes to amend certain portions of CBOE Rule 6.45A regarding allocation of trades on Hybrid. The first change is to expand the introductory paragraph definition of ''market participant'' to include RMMs. The second proposed change is to clarify in Paragraph (a), Allocation of Incoming Electronic Orders, that market participants may enter quotes or orders and receive allocations pursuant to the Ultimate Matching Algorithm.

The third proposed change is to amend paragraph (b), Allocation of Orders Represented in Open Outcry, to clarify that only in-crowd market participants would be eligible to participate in open outcry trade allocations. This is consistent with the prohibitions in CBOE Rules 8.4 and 8.7 that prevent an RMM from trading in open outcry. The Exchange also proposes to limit the duration of paragraph (b) to six months from the date of approval of this proposal, unless otherwise extended.

CBOE Rule 6.73 Responsibilities of Floor Brokers

The Exchange proposes to amend CBOE Rule 6.73(d) to require a Floor Broker holding an order for the account of a Market-Maker or Specialist to verbally identify the order as such in open outcry prior to requesting a quote.

Changes to CBOE Membership Rules (3.2, 3.3, and 3.8)

CBOE proposes to amend CBOE Rule 3.2 to make clear that a member is deemed to have an authorized trading function if the member is approved to act as a nominee or person registered for an RMM organization. This would ensure under CBOE Rule 3.9(g) that the RMM nominee completes CBOE's Member Orientation Program and passes CBOE's Trading Member Qualification Exam. The proposed amendments to CBOE Rules 3.2 and 3.3 would also clarify that a member may elect membership status as an RMM.

CBOE also proposes to amend CBOE Rule 3.8(a)(ii), which currently states that ''if the member organization is the owner or lessee of more than one such membership, the organization must designate a different individual to be the nominee for each of the memberships (except that this subparagraph would not apply to memberships designated for use in an e-DPM capacity pursuant to CBOE Rule 8.92 by a member organization approved as an e-DPM).'' New proposed CBOE Rule 3.8.02 would provide two exceptions to CBOE Rule 3.8(a)(ii) to accommodate the creation of RMMs. First, CBOE proposes to exclude RMMs from the CBOE Rule 3.8(a)(ii) requirement in the same manner as e-DPMs are excluded. As with e-DPMs, the CBOE Rule 3.8(a)(ii) requirement serves no useful purpose in the context of electronic access and market-making and may negatively affect an RMM member organization's operating structure by imposing upon it unnecessary expenses. To this end, CBOE proposes to restrict application of this rule such that it would not apply to memberships used in an RMM and e-DPM capacity. This would allow a member organization to designate one individual to be the nominee of the memberships that are designated for use in an RMM capacity and an e-DPM capacity, provided that a member organization may not have more than one RMM appointment in an option class (except to the extent provided in CBOE Rule 8.4(c)) and may not have an RMM appointment in an option class in which the organization serves as a DPM, e-DPM, or Market-Maker on the Exchange (except to the extent provided in CBOE Rule 8.4(c)).

New proposed CBOE Rule 3.8.02(ii) would also provide a second exception to CBOE Rule 3.8(a)(ii) to permit an individual to act as a nominee of an organization with respect to one membership utilized in an RMM capacity and a membership not utilized in an RMM or e-DPM capacity in order

to allow the nominee to use those memberships to simultaneously trade as an in-crowd Market-Maker and in an RMM capacity (but not in the same classes), provided that the RMM trading activity of the nominee is from a location other than the physical trading station for any of the classes traded by the nominee in an RMM capacity. CBOE represents that the purpose of this exception is to accommodate members who choose to take advantage of his or her remote market making privileges while on the Exchange floor.

2. Statutory Basis

The Exchange believes that the adoption of rules allowing for remote market making would attract and encourage member firms to provide supplemental liquidity to that currently provided on the floor by in-crowd market participants. Accordingly, the Exchange believes that the addition of RMMs would provide investors with deeper and more liquid markets. For these reasons, the Exchange believes the proposed rule change, as amended, is consistent with the Act and the rules and regulations under the Act applicable to a national securities exchange and, in particular, the requirements of Section 6(b) of the Act.[27] Specifically, the Exchange believes the proposed rule change, as amended, is consistent with the Section 6(b)(5)[28] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts 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 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 neither solicited nor received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, 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–2004–75 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–CBOE–2004–75. 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, 450 Fifth Street, NW., Washington, DC 20549. 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–2004–75 and should be submitted on or before February 25, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[29]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–429 Filed 2–3–05; 8:45 am]

BILLING CODE 8010–01–P

[27] 15 U.S.C. 78f(b).

[28] 15 U.S.C. 78f(b)(5).

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51101; File No. SR-CBOE–2005–09]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Board Options Exchange, Inc. To Amend its Marketing Fee Program To Provide for a Monthly Refund of Any Surplus

January 28, 2005.

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 January 14, 2005, the Chicago Board Options Exchange, Inc. (''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 prepared by the CBOE. The CBOE has designated this proposal as one establishing or changing a due, fee, or other charge imposed by the CBOE 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 CBOE proposes to amend its marketing fee program to provide for a monthly, rather than quarterly, refund of any surplus. Below is the text of the proposed rule change. Proposed new language is *italicized*; proposed deletions are in [brackets].

CHICAGO BOARD OPTIONS EXCHANGE, INC.

FEE SCHEDULE

1.–4. No change.

[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).

NOTES:

(1)–(5) No change.

(6) The Marketing Fee will be assessed only on transactions of Market-Makers, e-DPMs and DPMs at the rate of $.22 per contract on all classes of equity options, options on HOLDRs®, and options on SPDRs®. The fee will not apply to Market-Maker-to-Market-Maker transactions. This fee shall not apply to index options and options on ETFs (other than options on SPDRs). Should any surplus of the marketing fees at the end of each month occur, [those funds would be carried forward to the following month. T]the Exchange would then refund such surplus at the end of the *month*[quarter,] if any, on a pro rata basis based upon contributions made by the Market-Makers, e-DPMs and DPMs.

(7)–(14) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of and basis for its proposal and discussed any comments it had received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The 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

On October 29, 2004, the CBOE amended its marketing fee program.[5] The current marketing fee is assessed upon DPMs, e-DPMs, and Market-Makers at a rate of $0.22 for every contract they enter into on the Exchange, other than Market-Maker-to-Market-Maker transactions, including all transaction between any combination of DPMs, e-DPMs, and Market-Makers.[6] Currently, the marketing fee is assessed in all equity option classes, options on HOLDRs,[7] and options on SPDRs reg;.[8] Furthermore, should any surplus of the marketing fees at the end of each month occur, those funds are carried forward to the following month. The Exchange then refunds such surplus at the end of the quarter.

The Exchange now proposes to amend its marketing fee program to provide for a monthly, rather than quarterly, refund of any surplus.[9] The CBOE states that, based on its recent experience with the current marketing fee program, it now believes that a monthly, rather than quarterly, refund is more efficient for administrative purposes.[10] The Exchange states that, consistent with the current marketing fee program, it will continue to refund any surplus on a pro rata basis based upon contributions made by the Market-Makers, e-DPMs, and DPMs.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[11] in general, and furthers the objectives of Section 6(b)(4) of the Act[12] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among the CBOE's members.

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 CBOE neither solicited nor received written comments with respect to the proposed rule change.

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)(ii) of the Act[13] and subparagraph (f)(2) of Rule 19b–4 thereunder.[14] Accordingly, the proposal will take effect upon filing with the Commission. 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–CBOE–2005–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–CBOE–2005–09. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be

[5] *See* Securities Exchange Act Release No. 50736 (November 24, 2004), 69 FR 69966 (December 1, 2004) (SR–CBOE–2004–68) (''Release No. 34–50736'').

[6] *See* Release No. 34–50736 for a more detailed description of the CBOE's marketing fee program.

[7] HOLDRs are trust-issued receipts that represent an investor's beneficial ownership of a specified group of stocks. *See* Interpretation .07 to CBOE Rule 5.3.

[8] *See* Securities Exchange Act Release No. 51052 (January 18, 2005), 70 FR 3757 (January 26, 2005) (SR–CBOE–2005–05).

[9] The Exchange states that the Marketing Fee Oversight Committee will continue to conduct quarterly reviews of the marketing fee program, including aspects related surpluses and the program's effectiveness. Telephone conversation between Andrew Spiwak, Director Legal Division and Chief Enforcement Attorney, CBOE, and David Liu, Attorney, Division of Market Regulation (''Division''), Commission, on December 18, 2005.

[10] Telephone conversation between Andrew Spiwak, Director Legal Division and Chief Enforcement Attorney, CBOE, and David Liu, Attorney, Division, Commission, on December 18, 2005.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

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 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–2005–09 and should be submitted on or before February 25, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–432 Filed 2–3–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51095; File No. SR–FICC–2005–04]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Clarify Timing of Premium Assessment Pursuant to Rule 3 of the Government Securities Division for Violation of Minimum Financial Standards

January 28, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on January 25, 2005, the Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by FICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of the proposed rule change is to clarify that the premium to be assessed pursuant to Rule 3 of the Government Securities Division (''GSD'') for violation of minimum financial standards will begin to be assessed on the date FICC becomes aware of the violation.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FICC 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. FICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Recently, the Commission approved a proposed rule change by FICC to amend Rule 3 of the GSD to modify the penalty assessment process for violations of minimum financial standards.[3] Pursuant to a provision under GSD Rule 3, which is scheduled to become effective on January 31, 2005,[4] a violation of a minimum financial standard by certain netting members will result in the imposition of a clearing fund premium which will continue for ninety calendar days after the later of (i) the member's return to compliance with applicable minimum financial standards or (ii) FICC's discovery of the violation. The purpose of this proposed rule change is to clarify that the required clearing fund deposit premium that will be assessed pursuant to Rule 3 of the GSD for violation of minimum financial standards will be effective beginning on the day of the violation but will begin to be assessed on the date FICC becomes aware of the violation.

The proposed rule change is consistent with the requirements of Section 17A of the Act[5] and the rules and regulations thereunder applicable to FICC because it assures the safeguarding of securities and funds which are in the custody or control of FICC by encouraging participants to maintain their minimum financial standards and to submit their required financial reports on a timely basis. As a result, FICC's ability to maintain a financially sound participant base should be enhanced.

(B) Self-Regulatory Organization's Statement on Burden on Competition

FICC does not believe that the proposed rule change will have any impact on or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments relating to the proposed rule change have been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing 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)[7] thereunder because the proposed rule constitutes an interpretation with respect to the meaning, administration, or enforcement of an existing rule. At any time within sixty days of the filing of such 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–FICC–2005–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–FICC–2005–04. This file

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by FICC.

[3] Securities Exchange Act Release No. 50659 (November 15, 2004), 69 FR 67767 (November 19, 2004) [File No. SR–FICC–2004–11].

[4] This effective date was announced to the GSD's members in Important Notice GOV.156.04 (November 22, 2004) which is available on FICC's Web site at *http://www.ficc.com.*

[5] 15 U.S.C. 78q–1.

[6] 15 U.S.C. 78s(b)(3)(A)(i).

[7] 17 CFR 240.19b–4(f)(1).

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, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of FICC and on FICC's Web site at *http://www.ficc.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–FICC–2005–04 and should be submitted on or before February 25, 2005.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–430 Filed 2–3–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51103; File No. SR–ISE–2005–04]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the International Securities Exchange, Inc. Relating to Fee Changes

January 28, 2005.

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 January 7, 2005, the International Securities Exchange, Inc. (''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 prepared by the ISE. The ISE has designated this proposal as one establishing or changing a due, fee, or other charge imposed by the ISE 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 provide that the payment for order flow fee shall not apply to market makers when executing against Public Customer Orders entered into the Exchange's Price Improvement Mechanism (''PIM''). The text of the proposed rule change is available on the ISE's Web site (*http://www.iseoptions.com*), at the principal office of 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 its proposal and discussed any comments it had received regarding the proposal. 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 ISE states that the purpose of this proposed rule change is to amend the ISE Schedule of Fees to provide that the payment for order flow fee shall not apply to market makers when executing against Public Customer Orders entered into the Exchange's PIM. According to the ISE, the Exchange's PIM, the rules for which were recently approved by the Commission,[5] will permit an Electronic Access Member (''EAM'') to seek price improvement for its Public Customer Orders in amounts smaller than the standard nickel and dime trading increments. The PIM grants an EAM a preference at the best price for trading against at least a portion of its order, but allows other members to compete for that order by providing price improvement. The ISE states that, because market makers will be providing price improvement to Public Customer Orders when trading in the PIM, the Exchange will also not charge market makers a payment for order flow fee on these trades. Thus, the Exchange proposes to exempt PIM executions from the $.55 per contract payment for order flow fee charged to market markers when executing against Public Customer Orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[6] in general, and furthers the objectives of Section 6(b)(4) of the Act[7] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

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 ISE neither solicited nor received written comments with respect to the proposed rule change.

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)(ii) of the Act[8] and subparagraph (f)(2) of Rule 19b–4 thereunder.[9] Accordingly, the proposal will take effect upon filing with the Commission. 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,

[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)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* Securities Exchange Act Release No. 50819 (December 8, 2004), 69 FR 75093 (December 15, 2004) (SR–ISE–2003–06).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 240.19b–4(f)(2).

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–ISE–2005–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–ISE–2005–04. 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 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–2005–04 and should be submitted on or before February 25, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–433 Filed 2–3–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51092; File No. SR–NASD–2004–159]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing of Proposed Rule Change To Allow NASD To Review on a Pilot Basis Denial of Access Complaints Related to the Alternative Display Facility

January 28, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 22, 2004, the National Association of Securities Dealers, Inc. (''NASD'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD. On January 11, 2005, NASD filed Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASD is proposing to establish on a pilot basis new NASD Rule 4400A, which would give NASD the authority to receive and review complaints against an NASD Market Participant[4] alleging denial of direct or indirect access of the NASD Market Participant's quotations in the Alternative Display Facility (''ADF'') that the NASD Market Participant is required to provide pursuant to NASD Rule 4300A. In addition, proposed NASD Rule 4400A would set forth the procedures and review process for such complaints. Finally, the proposal would delegate authority to NASD's Market Regulation Committee to review denial of access determinations rendered in accordance with Rule 4400A. The text of the proposed rule change is available on NASD's Web site (*http://www.nasd.com*), at the principal offices of NASD, 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, NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. NASD 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

Background

On July 24, 2002, the Commission approved SR–NASD 2002–97, which authorizes NASD to operate the ADF on a pilot basis for nine months.[5] NASD subsequently filed for immediate effectiveness proposed rule changes to extend the pilot, the most recent until July 26, 2005.[6] The ADF is a quotation collection, trade comparison, and trade reporting facility developed by NASD in accordance with the Commission's SuperMontage Approval Order[7] and in conjunction with Nasdaq's proposal to register as a national securities exchange.[8]

Under the pilot, the ADF provides NASD Market Participants the ability to post quotations in Nasdaq securities and provides all members that participate in the ADF the ability to view quotations and report transactions in Nasdaq securities to the exclusive Securities

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange clarified the scope of authority granted to the NASD and the Market Regulation Committee to review denials of access. Amendment No. 1 replaced the original filing in its entirety.

[4] *See* NASD Rule 4300A(d)(4) defining ''NASD Market Participant'' as: (a) A NASD Registered Reporting ADF Market Maker (defined in NASD Rule 4200A(10); (b) an alternative trading system or ''ATS''; or (c) an NASD ADF Registered electronic communication network or ''ECN.''

[5] *See* Securities Exchange Act Release No. 46249 (July 24, 2002), 67 FR 49822 (July 31, 2002).

[6] *See* Securities Exchange Act Release Nos. 47663 (April 10, 2003), 68 FR 19043 (April 17, 2003) (SR–NASD–2003–67); 49131 (January 27, 2004), 69 FR 5229 (February 3, 2004) (SR–NASD–2004–12); 50601 (October 28, 2004), 69 FR 64611 (November 5, 2004) (SR–NASD–2004–160).

[7] Securities Exchange Act Release No. 43863 (January 19, 2001), 66 FR 8020 (January 26, 2001) (SR–NASD–99–53).

[8] Securities Exchange Act Release No. 44396 (June 7, 2001), 66 FR 31952 (June 13, 2001) (File No. 10–131).

Information Processor (''SIP'') for Nasdaq-listed issues [9] for consolidation and dissemination of data to vendors and ADF market participants. The facility also provides for trade comparison through the Trade Reporting and Comparison Service or ''TRACS.'' The facility further provides for real-time data delivery to NASD for regulatory purposes, including enforcement of firm quote and related rules.

Order Access Rule

The ADF does not provide an order routing capability. Instead, pilot NASD Rule 4300A requires an NASD Market Participant to provide direct electronic access to other NASD Market Participants and to provide to all other NASD members direct electronic access or allow for indirect electronic access to its quotations in the ADF. This rule provides the means for NASD Market Participants and other broker-dealers to access ADF quotes and, among other things, to meet the firm quote and locked-and-crossed quotation requirements.

Authority and Review Procedures

The proposed rule change would give NASD the authority to receive and review complaints against an NASD Market Participant alleging denial of direct or indirect access required by NASD Rule 4300A. According to NASD, the proposed rule change is not intended to include complaints that allege: (1) A denial of direct or indirect access because of non-payment of fees for access to an NASD Market Participant's quotations that are imposed by the NASD Market Participant in accordance with SEC rules and regulations or otherwise; or (2) a specific instance or group of instances over discrete time periods where an NASD Market Participant is alleged not to have not honored its quotation in accordance with applicable SEC and NASD rules with respect to orders received electronically pursuant to NASD Rule 4300A.[10] Under the proposed rule change, the process for proper denial of access complaints would be as follows:

The complainant would be required to file a written complaint with ADF Operations via facsimile, personal delivery, courier, or overnight mail that specifically alleges denial of access to an NASD Market Participant's quotation. The complainant would be required to serve a copy of the complaint by the same means on the opposite party in accordance with NASD Rule 9134(b).

The denial of access complaint would be reviewed by an officer designated by a President of NASD or one its divisions to make a determination on the merits of the complaint. The officer could, at his or her discretion, conduct further investigation before rendering a decision as to whether there had been a denial of access in contravention of NASD Rule 4300A. In the event that the officer determined that there had been a denial of access in contravention of NASD Rule 4300A, he or she would direct the offending party to provide access to ADF quotes and could limit participation in the ADF by such party if it did not comply promptly with the directive to provide access. The directive and any action to limit participation in the ADF would become effective and remain in place during the pendency of any further review or appeal.

The proposed rule change also would provide for a review of this initial determination by a three-member subcommittee consisting of current or former members of NASD's Market Regulation Committee (''MRC'').[11] A party seeking such review would be required to submit a written appeal to NASD by the close of business on the next business day after receipt of the initial determination and simultaneously to serve a copy of the written appeal to the opposite party. The party seeking review would be accorded 24 hours, or a longer period determined by NASD staff, after submission of the appeal to provide NASD and the opposing party any supporting written information concerning the appeal. The opposing party would then have 24 hours, or a longer period determined by NASD staff, to submit written documentation in support of its position. A three-member subcommittee of current or former MRC members would then render a final determination to affirm or reverse the determination of the NASD officer based on the record and any hearing it shall, in its discretion, determine to hold.

The proposal would require the MRC subcommittee to provide written notification of its decision by the close of business the day following its determination. The decision, including affirmation of any directive to provide access or action to limit participation in the ADF rendered by the NASD officer, would be effective upon issuance of the written decision and remain in effect during the pendency of further appeals or other legal proceedings. The MRC subcommittee could not impose any additional sanctions, including monetary fines; its authority would be limited to affirming or reversing the determination of the NASD officer.

The MRC decision would constitute final NASD action, which could be appealed to the Commission. The decision would not prejudice the rights of the parties to subsequently submit the matter to arbitration or another adjudicatory forum as appropriate. Furthermore, the decision would not operate as an estoppel or otherwise bind NASD in any subsequent disciplinary action or other legal proceeding. Amendment No. 1 to the proposed rule change clarifies the scope of the authority granted to NASD and its MRC to review alleged denial of access complaints pursuant to NASD Rule 4300A and limits the remedies that may be imposed as part of the review.

Plan of Allocation and Delegation to Subsidiaries

Pursuant to Article XIII, Section 1 of the NASD By-Laws, the Board of Governors is vested with the authority to limit the activities, functions, and operations of members for failure to comply with NASD rules. Section 2 of Article XIII permits the Board of Governors to delegate that authority. In accordance with those provisions, the proposed rule change also would amend the Plan of Allocation and Delegation to Subsidiaries to expressly delegate to the MRC the authority to review denial of access determinations in accordance with the NASD Rule 4000A Series.

If the Commission approves the proposal, NASD would announce the effective date of the new rule in a Notice to Members to be published no later than 60 days following Commission approval. The effective date would be 30 days following publication of the Notice to Members announcing Commission approval.

2. Statutory Basis

NASD believes that the proposed rule change, as amended, is consistent with the provisions of Section 15A(b)(6) of

[9] Nasdaq initially will be the designated SIP for all transactions and quotations in Nasdaq securities. During the pilot period, the SIP will distribute individual quotations for both ADF and Nasdaq market makers and ECNs.

[10] NASD's Market Regulation Department has established a real-time process to receive, evaluate, and act upon firm quote complaints.

[11] The Market Regulation Committee is an NASD committee that considers the federal securities laws and the rules and regulations adopted thereunder and various NASD Rules and policies relating to: (1) The quotations of securities, (2) the executions of transactions, (3) the reporting of transactions; and (4) trading practices and rules. *See* NASD Rule 9120(s).

the Act,[12] which requires, among other things, that NASD's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that the procedures to hear denial of access complaints would maintain the integrity of the ADF and provide a fair process for review.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change, as amended, would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, 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-NASD–2004–159 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR-NASD–2004–159. 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 NASD. 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-NASD–2004–159 and should be submitted on or before February 25, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–431 Filed 2–3–05; 8:45 am]

BILLING CODE 8010–01–P

[12] 15 U.S.C. 78o–3(b)(6).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51102; File No. SR–PCX–2004–118]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto by the Pacific Exchange, Inc. Relating to Arbitration Fees

January 28, 2005.

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 December 2, 2004, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On January 28, 2005, the Exchange filed Amendment No. 1 to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

PCX is proposing to amend the PCX Options and PCX Equities, Inc. arbitration fees (''Options Fees'' and ''PCXE Fees,'' respectively) with respect to fees that only affect OTP Holders and OTP Firms[3] and ETP Holders.[4] The text of the proposed rule change is available on the PCX Web site (*http://www.pacificex.com/legal/docs/prf/2004/SR–PCX–2004–118.pdf*), at the principal office of the PCX, 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, 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

Purpose

The Exchange proposes to amend its arbitration fees with respect to OTP Holders and Firms and ETP Holders to increase and, in some instances, add arbitration-related fees. The proposed amendments are based on the National Association of Securities Dealers' (''NASD's'') arbitration fees.

The Exchange's arbitration program offers a comparable level of service to that of the NASD and is one of the competing forums for securities arbitration. The Exchange sought to amend its fees in 2002,[5] but due to the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* PCX Rule 1(q)–(r).

[4] *See* PCXE Rule 1(n).

[5] *See* SR–PCX–2002–45.

uncertainty of arbitration programs in California, the Exchange withdrew the filing and retained its then-current fee structure. As a result, the Exchange's arbitration fees remain deficient as compared to the fees that other self-regulatory organizations charge for arbitration. Thus, the Exchange proposes to modify its fees with respect to OTP Holders and OTP Firms and ETP Holders in order to bring its fees in line with competing forums as well as recover costs associated with the PCX arbitration program.

1. OTP Firm or OTP Holder Controversies/ETP Controversies

The Exchange proposes to amend the fee schedules applicable to ''OTP Firm or OTP Holder Controversies'' under PCX Rule 12.31 for the Options Fees and ''ETP Holder Controversies'' under PCXE Rule 12.32 for the PCXE Fees. These fee schedules apply to cases that are between OTP Holders and Firms or associated persons thereof, or between ETP Holders or associated persons thereof. The Exchange proposes to modify the required fee for the Amount in Dispute, Filing Fee, Simplified (No Hearing) Fee, and the Hearing Session Deposit. These fee modifications are identical to the current fees imposed at the NASD.[6]

2. Pre-Hearing and Hearing Process Fees

The Exchange proposes new PCX Rule 12.33 and new PCXE Rule 12.32(k) to adopt pre-hearing and hearing process fees that mirror the fees charged by the NASD.[7] The Exchange proposes that each OTP Holder, OTP Firm, or ETP Holder that is a party to an arbitration proceeding in which more than $25,000 is in dispute pay a non-refundable pre-hearing process fee of $750, due at the time the parties are sent notification of the arbitration panel. Thereafter, a non-refundable hearing process fee will be due when the parties are notified of the date and location of the first hearing session in accordance with the proposed hearing process fee schedule. If an associated person of an OTP Holder, OTP Firm or ETP Holder is a party, the OTP Holder, OTP Firm, or the ETP Holder that employed the associated person at the time of the events which gave rise to the dispute, claim or controversy will be charged the process fees, even if the OTP Holder, OTP Firm, or ETP Holder is not a party.

These processing fees will bring revenue to the Exchange and compensate the Exchange at an earlier stage of the arbitration process. The processing fees are particularly important because much of the time and money spent by the Exchange to administer cases is required during the first months of the arbitration process.

3. Surcharge

The Exchange proposes to amend PCX Rule 12.32(c) and PCXE Rule 12.33(c) in order to modify the OTP Holder/OTP Firm Surcharge and ETP Holder Surcharge, respectively. The surcharge will continue to be based on the amount in dispute. The Exchange proposes to amend PCX Rule 12.32(a) and PCXE Rule 12.33(a) to provide that these surcharges may be refundable in an arbitration filed by a customer if the arbitration panel: (1) Denies all of the customer's claims against the OTP Holder, OTP Firm, ETP Holder, or associated person, and (2) allocates all forum fees assessed pursuant to PCX Rule 12.31 or PCXE Rule 12.32 against the customer. The Director may also refund or cancel the OTP Holder/OTP Firm Surcharge or the ETP Holder Surcharge in other extraordinary circumstances. The Exchange believes it is appropriate to modify the surcharge in order to bring the surcharge up to date and ensure sufficient cost recovery associated with the PCX arbitration program.

Basis

The Exchange believes that the proposal is consistent with Section 6(b)[8] of the Act, in general, and Section 6(b)(4)[9] of the Act, in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among the Exchange's OTP Holders, OTP Firms, ETP Holders, and other persons using the Exchange's facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to Section 19(b)(3)(A)[10] of the Act and subparagraph (f) of Rule 19b–4 thereunder,[11] because the proposed rule change establishes or changes a due, fee, or other charge applicable only to a member of the Exchange. 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 purpose of the Act.[12]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, 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–PCX–2004–118 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File No. SR–PCX–2004–118. 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

[6] *See* NASD Rule 10205(k).

[7] *See* NASD Rule 10333(b).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f).

[12] For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change under Section 19(b)(3)(C) of the Act, the Commission considers that period to commence on January 28, 2005, the date on which the Exchange filed Amendment No. 1 to the proposed rule change. *See* 15 U.S.C. 78s(b)(3)(C).

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, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of such filing will also be available for inspection and copying at the principal office of the PCX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–PCX–2004–118 and should be submitted on or before February 25, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–434 Filed 2–3–05; 8:45 am]

BILLING CODE 8010–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Public Comment Regarding Andean Trade Promotion and Drug Eradication Act (ATPDEA) Beneficiary Countries

AGENCY: Office of the United States Trade Representative.

ACTION: Notice; request for comments.

SUMMARY: In compliance with section 203(f) of the Andean Trade Preference Act (ATPA) (19 U.S.C. 3201), as amended by the Andean Trade Promotion and Drug Eradication Act , the Office of the United States Trade Representative (USTR) is requesting the views of interested parties on whether the countries designated as ATPA beneficiary countries in Presidential Proclamation 7616 of October 31, 2002, are meeting the eligibility criteria provided for in section 204(b)(6)(B) of the ATPA. This information will be used in the preparation of a report to the U.S. Congress on the operation of the program.

DATES: Public comments are due at USTR no later than 5 p.m., March 18, 2005.

ADDRESSES: *Submissions by electronic mail: FR0518@USTR.EOP.GOV.* *Submissions by facsimile:* Gloria Blue, Executive Secretary, Trade Policy Staff Committee, at (202) 395–6143. The public is strongly encouraged to submit documents electronically rather than by facsimile. See requirements for submissions below.

FOR FURTHER INFORMATION CONTACT: Russell Smith, Office of the Americas, Office of the United States Trade Representative, 600 17th Street, NW., Room 523, Washington, DC 20508. The telephone number is (202) 395–9450.

SUPPLEMENTARY INFORMATION: Signed into law on August 6, 2002, the Trade Act of 2002 contains, in title XXXI, provisions for enhanced trade benefits for eligible Andean countries. Titled the ''Andean Trade Promotion and Drug Eradication Act'' (ATPDEA), the ATPDEA renews the Andean Trade Preference Act (ATPA), and amends the ATPA to provide preferential treatment for certain products previously excluded from such treatment. In Presidential Proclamation 7616 of October 31, 2002, the President designated Bolivia, Colombia, Ecuador and Peru as ATPA beneficiary countries. Section 203(f) of the ATPA requires the USTR, not later than April 30, 2005, to submit to Congress a report on the operation of the ATPA. Section 203(f)(2) requires USTR, before submitting such report, to request comments on whether beneficiary countries are meeting the criteria set forth in section 204(b)(6)(B) (which incorporates by reference the criteria set forth in sections 203(c) and (d)). USTR refers interested parties to the **Federal Register** notice published on August 15, 2002 (67 FR 53379), for a full list of the eligibility criteria.

Requirements for Submissions. In order to facilitate prompt processing of submissions, the Office of the United States Trade Representative strongly urges and prefers electronic (e-mail) submissions in response to this notice. In the event that an e-mail submission is impossible, submissions should be made by facsimile.

Persons making submissions by e-mail should use the following subject line: ''ATPA Beneficiary Countries.'' Documents should be submitted as either WordPerfect, MSWord, or text (.TXT) files. Spreadsheets submitted as supporting documentation are acceptable as Quattro Pro or Excel files. If any document submitted electronically contains business confidential information, the file name of the business confidential version should begin with the characters ''BC-,'' and the file name of the public version should begin with the characters ''P-.'' The ''P-'' or ''BC-'' should be followed by the name of the submitter. Persons who make submissions by e-mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. To the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Written comments, notice of testimony, and testimony will be placed in a file open to public inspection pursuant to 15 CFR 2003.5, except business confidential information exempt from public inspection in accordance with 15 CFR 2003.6. Business confidential information submitted in accordance with 15 CFR 2003.6 must be clearly marked ''BUSINESS CONFIDENTIAL'' at the top of each page, including any cover letter or cover page, and must be accompanied by a non-confidential summary of the confidential information. All public documents and non-confidential summaries shall be available for public inspection in the USTR Reading Room. The USTR Reading Room is open to the public, by appointment only, from 10 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday. An appointment to review the file must be scheduled at least 48 hours in advance and may be made by calling (202) 395–6186.

Carmen Suro-Bredie,

Chairman, Trade Policy Staff Committee.

[FR Doc. 05–2188 Filed 2–3–05; 8:45 am]

BILLING CODE 3190–W5–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of List of Products Subject to Possible Withdrawal of Concessions in Response to European Union (EU) Changes to Its Rice Import Regime

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: In response to the European Union's changes to its rice import regime, the United States has notified the World Trade Organization of its intent to withdraw concessions by March 1, 2005, with respect to the goods in the attached list.

Background: In **Federal Register** notices 04–20543, dated September 10, 2004, 04–21762 and dated September 28, 2004, the Office of the U.S. Trade Representative sought comments concerning a list of goods for which tariff concessions may be withdrawn and duties may be increased in the

[13] 17 CFR 200.30–3(a)(12).

event the United States cannot reach agreement with the European Union (EU) for adequate compensation owed under World Trade Organization (WTO) rules as a result of EU changes to its rice import regime.

While the United States Government has actively sought a negotiated resolution of this issue, which would have alleviated the need to withdraw concessions, an agreement has not been reached. Therefore, in accordance with WTO rules, the United States has notified the WTO that it will withdraw substantially equivalent tariff concessions if an agreement is not reached before March 1.

This notice provides the list of goods notified to the WTO on Friday, January 28, 2005.

Whenever a foreign country withdraws, suspends, or modifies the application of trade agreement obligations of benefit to the United States without granting adequate compensation, the President is authorized under section 125(c) of the Trade Act of 1974 (19 U.S.C. 2135) to proclaim such increased duties or other import restrictions as are appropriate to effect adequate compensation. In the event that the United States withdraws substantially equivalent tariff concessions on March 1, increases in the duties applied to the goods included in the list notified to the WTO would be effected pursuant to this authority.

FOR FURTHER INFORMATION CONTACT: Sharon Sydow, Director for Agricultural Trade Policy, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20508; telephone (202) 395–6127.

Carmen Suro-Bredie,

Chair, Trade Policy Staff Committee.

Attachment: List of Products Subject to Possible Withdrawal of Concessions in Response to European Union (EU) Changes to Its Rice Import Regime

HS code	Product
04031090	Yogurt, not in dry form, whether or not flavored or containing add fruit or cocoa.
04063085	Processed cheese (incl. mixtures), nesoi, n/o 0.5% by wt. butterfat, not grated or powdered, subject to Ch4 U.S. note 23, not GN15.
07052100	Witloof chicory, fresh or chilled.
07108065	Brussels sprouts, uncooked or cooked by steaming or boiling in water, frozen, not reduced in size.
08052000	Mandarins (including tangerines and satsumas); clementines, wilkings and similar citrus hybrids, fresh or dried.
09042020	Paprika, dried or crushed or ground.
09102000	Saffron.
20019025	Artichokes, prepared or preserved by vinegar or acetic acid.
20032000	Truffles, prepared or preserved otherwise than by vinegar or acetic acid.
20049010	Antipasto, prepared or preserved otherwise than by vinegar or acetic acid, frozen.
20057050	Olives (not green) in a saline solution, canned, not pitted.
20057070	Olives (not green), in a saline solution, in airtight containers of glass or metal but not canned.
20057075	Olives (not green) in a saline solution, not canned, nesoi.
20059030	Sauerkraut, prepared or preserved otherwise than by vinegar or acetic acid, not frozen.
20087020	Peaches (excluding nectarines), otherwise prepared or preserved, not elsewhere specified or Included.

Note: The product descriptions supplied above for the items of the Harmonized Tariff Schedule of the United States (''HTS'') are for the convenience of the reader and are not intended to delimit in any way the scope of the products that would be subject to increased duties.

[FR Doc. 05–2196 Filed 2–3–05; 8:45 am]

BILLING CODE 3190–W5–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

January 25, 2005.

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 March 7, 2005 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1394.

Form Number: IRS Form 1120–SF.

Type of Review: Extension.

Title: U.S. Income Tax Return for Settlement Funds (Under Section 468B).

Description: Form 1120–SF is used by settlement funds to report income and taxes on earnings of the fund. The fund may be established by court order, a breach of contract, a violation of law, an arbitration panel, or the Environmental Protection Agency. The IRS uses Form 1120–F to determine if income and taxes are correctly computed.

Respondents: Business or other for-profit.

Estimated Number of Respondents/ Recordkeepers: 1,000.

Estimated Burden Hours Respondent/ Recordkeeper:

Recordkeeping—18 hr., 24 min.
Learning about the law or the form—2 hr., 49 min.
Preparing the form—5 hr., 6 min.
Copying, assembling, and sending the form to the IRS—32 min.

Frequency of response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 26,880 hours.

OMB Number: 1545–1423.

Regulation Project Number: PS–106–91 Final.

Type of Review: Extension.

Title: State Housing Credit Ceiling and Other Rules Relating to the Low-Income Housing Credit.

Description: The regulations provide the order in which credits are allocated from each State's credit ceiling under section 422(h)(3)© and the determination of which states qualify for credits from a National Pool of credits under section 42(h)(3)(D). Allocating agencies need this information to correctly allocate credits and determine National Pool eligibility.

Respondents: Business or other for-profit, Individuals or households. Not-for-profit institutions, State, Local or Tribal Government.

Estimated Number of Respondents: 110.

Estimated Burden Hours Respondent: 2 hours, 30 minutes.

Frequency of response: Other (one time per event).

Estimated Total Reporting Burden: 275 hours.

OMB Number: 1545–1478.

Regulation Project Number: INTL–9–95 Final.

Type of Review: Extension.

Title: Certain Transfers of Domestic Stock or Securities by U.S. Persons to Foreign Corporations.

Description: Transfers of stock or securities by U.S. persons in tax-free transactions are treated as taxable transactions when the acquirer is a foreign corporation, unless an exception applies (section 367(a)). Under the regulations, no U.S. person will qualify for an exception unless the U.S. target company complies with certain reporting requirements.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 100.

Estimated Burden Hours Respondent: 10 hours.

Frequency of Response: Other (once).

Estimated Total Reporting Burden: 1,000 hours.

OMB Number: 1545–1634.

Regulation Project Number: REG–106902–98 Final.

Type of Review: Extension.

Title: Consolidated Returns—Consolidated Overall Foreign Losses and Separate Limitation Losses.

Description: The regulations provide guidance relating to the amount of overall foreign losses and separate limitation losses in the computation of the foreign tax credit. The regulations affect consolidated groups of corporations that compute the foreign tax credit limitation or that disposes of property used in a foreign trade or business.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 2,000.

Estimated Burden Hours Respondent: 1 hour, 30 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 3,000 hours.

OMB Number: 1545–1750.

Form Number: IRS Form 8038–R.

Type of Review: Extension.

Title: Request for Recovery of Overpayments under Arbitrage Rebate Provisions.

Description: Under Treasury Regulations section 1.148–3(i), bond issuers may recover an overpayment of arbitrage rebate paid to the United States under Internal Revenue Code section 148. Form 8038–R is used to request recovery of any overpayment of arbitrage rebate made under the arbitrage rebate provisions.

Respondents: State, Local or Tribal Government.

Estimated Number of Respondents/Recordkeepers: 200.

Estimated Burden Hours Respondent/Recordkeeper:

Recordkeeping—5 hr., 44 min.

Learning about the law or the form—3 hr., 16 min.

Preparing, copying, assembling, and sending the form to the IRS—3 hr., 30 min.

Frequency of Response: On occasion.

Estimated Total Reporting/Recordkeeping Burden: 2,458 hours.

Clearance Officer: Paul H. Finger, Internal Revenue Service, Room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224, (202) 622–3634.

OMB Reviewer: Joseph F. Lackey, Jr., Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, (202) 395–7316.

Lois K. Holland,

Treasury PRA Clearance Officer.

[FR Doc. 05–2167 Filed 2–3–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons

AGENCY: Department of the Treasury.

ACTION: Notice of final guidance.

SUMMARY: The Department of the Treasury is publishing its final policy guidance on the prohibition in Title VI of the Civil Rights Act of 1964 against national origin discrimination as it affects limited English proficient (LEP) persons. This policy guidance replaces policy guidance published March 7, 2001 and republished on March 7, 2002. On December 22, 2003, the Department published proposed guidance for public comment. No comments were received.

FOR FURTHER INFORMATION CONTACT: Pamela Proctor, Office of Equal Opportunity and Diversity, Department of the Treasury, 1750 Pennsylvania Avenue, NW., Room 8127 Washington, DC 20220; (202) 622–0324.

SUPPLEMENTARY INFORMATION: Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, *et seq.* provides that no person shall be subjected to discrimination on the basis of race, color, or national origin under any program or activity that receives Federal financial assistance.

Treasury's initial guidance regarding Title VI was published on March 7, 2001. *See* 66 FR 13829. The document was based on the policy guidance issued by the Department of Justice entitled ''Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons with Limited English Proficiency.'' 65 FR 50123 (August 16, 2000).

On October 26, 2001 and January 11, 2002, the Assistant Attorney General for Civil Rights issued to Federal departments and agencies guidance memoranda that reaffirmed the Department of Justice's (DOJ) commitment to ensuring that federally assisted programs and activities fulfill their LEP responsibilities, and which clarified and answered certain questions raised regarding the August 16, 2000 guidance. In furtherance of those memoranda, the Department of the Treasury republished its guidance for the purpose of obtaining additional public comment on March 7, 2002. *See* 67 FR 10477.

On March 14, 2002, following republication of Treasury's policy guidance, the Office of Management and Budget (OMB) issued a Report to Congress titled ''Assessment of the Total Benefits and Costs of Implementing Executive Order No. 13166: Improving Access to Services for Persons with Limited English Proficiency.'' Among other things, the Report recommended the adoption of uniform guidance by all Federal agencies, with flexibility to permit each agency to tailor its guidance to its specific customers. Consistent with this OMB recommendation, DOJ published LEP Guidance for DOJ recipients that was drafted and organized to also function as a model for similar guidance by other Federal agencies. *See* 67 FR 41455 (June 18, 2002). To the extent appropriate, Treasury's final guidance is consistent with the LEP guidance document published by DOJ.

The text of the complete final guidance document appears below.

Dated: December 21, 2004.

Jesus H. Delgado-Jenkins,

Acting Assistant Secretary for Management.

I. Introduction

Most individuals living in the United States read, write, speak and understand English. There are many individuals, however, for whom English is not their primary language. For instance, based on the 2000 census, over 26 million individuals speak Spanish and almost 7 million individuals speak an Asian or Pacific Island language at home. If these individuals have a limited ability to

read, write, speak, or understand English, they are limited English proficient, or ''LEP.'' While detailed data from the 2000 census has not yet been released, 26% of all Spanish-speakers, 29.9% of all Chinese-speakers, and 28.2% of all Vietnamese-speakers reported that they spoke English ''not well'' or ''not at all'' in response to the 1990 census.

Language for LEP individuals can be a barrier to accessing important benefits or services, understanding and exercising important rights, complying with applicable responsibilities, or understanding other information provided by federally funded programs and activities. The Federal Government funds an array of services that can be made accessible to otherwise eligible LEP persons. The Federal Government is committed to improving the accessibility of these programs and activities to eligible LEP persons, a goal that reinforces its equally important commitment to promoting programs and activities designed to help individuals learn English. Recipients should not overlook the long-term positive impacts of incorporating or offering English as a Second Language (ESL) programs in parallel with language assistance services. ESL courses can serve as an important adjunct to a proper LEP plan. However, the fact that ESL classes are made available does not obviate the statutory requirement to provide meaningful access for those who are not yet English proficient. Recipients of Federal financial assistance have an obligation to reduce language barriers that can preclude meaningful access by LEP persons to important government services.[1]

In certain circumstances, failure to ensure that LEP persons can effectively participate in or benefit from federally assisted programs and activities may violate the prohibition under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d . The purpose of this policy guidance is to assist recipients in fulfilling their responsibilities to provide meaningful access to LEP persons under existing law. This policy guidance clarifies existing legal requirements for LEP persons by providing a description of the factors recipients should consider in fulfilling their responsibilities to LEP persons.[2] These are the same criteria Treasury will use in evaluating whether recipients are in compliance with Title VI.

Before discussing these criteria in greater detail, it is important to note two basic underlying principles. First, we must ensure that federally-assisted programs aimed at the American public do not leave some behind simply because they face challenges communicating in English. This is of particular importance because, in many cases, LEP individuals form a substantial portion of those encountered in federally-assisted programs. Second, we must achieve this goal while finding constructive methods to reduce the costs of LEP requirements on small businesses, small local governments, or small non-profits that receive Federal financial assistance. There are many productive steps that the Federal Government, either collectively or as individual grant agencies, can take to help recipients reduce the costs of language services without sacrificing meaningful access for LEP persons. Without these steps, certain smaller grantees may well choose not to participate in federally assisted programs, threatening the critical functions that the programs strive to provide. To that end, the Department of the Treasury, in conjunction with the Department of Justice (DOJ), plans to continue to provide assistance and guidance in this important area. In addition, Treasury plans to work with its recipients and LEP persons to identify and share model plans, examples of best practices, and cost-saving approaches. Moreover, Treasury intends to explore how language assistance measures, resources and cost-containment approaches developed with respect to its own federally conducted programs and activities can be effectively shared or otherwise made available to recipients, particularly small businesses, small local governments, and small non-profits. An interagency working group on LEP has developed a Web site, *http://www.lep.gov,* to assist in disseminating this information to recipients, Federal agencies, and the communities being served.

Many commentators have noted that some have interpreted the case of *Alexander* v. *Sandoval,* 532 U.S. 275 (2001), as impliedly striking down the regulations promulgated under Title VI that form the basis for the part of Executive Order 13166 that applies to federally assisted programs and activities. Treasury and the Department of Justice have taken the position that this is not the case, and will continue to do so. Accordingly, we will strive to ensure that federally assisted programs and activities work in a way that is effective for all eligible beneficiaries, including those with limited English proficiency.

II. Legal Authority

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that no person shall ''on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.'' Section 602 authorizes and directs Federal agencies that are empowered to extend Federal financial assistance to any program or activity ''to effectuate the provisions of [section 601] * * * by issuing rules, regulations, or orders of general applicability.'' 42 U.S.C. 2000d–1.

Agency regulations promulgated pursuant to Section 602 of Title VI universally forbid recipients from ''utiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular race, color, or national origin.'' *See, e.g.,* 28 CFR 42.104(b) (2) (DOJ), 7 CFR 15.3(b) (2) (Department of Agriculture), 34 CFR 100.3(b) (2) (Department of Education), 45 CFR 80.3(b) (2) (Department of Health and Human Services), and 45 CFR 1110.3(b) (2) (National Endowment for the Arts and Humanities). Treasury has not yet, but intends to, issue regulations implementing Title VI. These will be consistent with this long-standing Federal policy prohibiting the use of criteria or methods of administration which have the effect of discriminating on the basis of race, color, or national origin.

The Supreme Court, in *Lau* v. *Nichols,* 414 U.S. 563 (1974), interpreted regulations promulgated by the former Department of Health, Education, and Welfare, including language identical to that quoted above, to hold that Title VI prohibits conduct that has a

[1] Treasury recognizes that many recipients may have had language assistance programs in place prior to the issuance of Executive Order 13166. This policy guidance provides a uniform framework for a recipient to integrate, formalize, and assess the continued vitality of these existing and possibly additional reasonable efforts based on the nature of its program or activity, the current needs of the LEP populations it encounters, and its prior experience in providing language services in the community it serves.

[2] The policy guidance is not a regulation but rather a guide. Title VI requires that recipients take reasonable steps to ensure meaningful access by LEP persons. This guidance provides an analytical framework that recipients may use to determine how best to comply with statutory and regulatory obligations to provide meaningful access to the benefits, services, information, and other important portions of their programs and activities for individuals who are limited English proficient.

disproportionate effect on LEP persons because such conduct constitutes national-origin discrimination. In Lau, a San Francisco school district that had a significant number of non-English speaking students of Chinese origin was required to take reasonable steps to provide them with a meaningful opportunity to participate in federally funded educational programs.

On August 11, 2000, Executive Order 13166 was issued. ''Improving Access to Services for Persons with Limited English Proficiency,'' 65 FR 50121 (August 16, 2000). Under that order, every Federal agency that provides financial assistance to non-Federal entities must publish guidance on how their recipients can provide meaningful access to LEP persons and thus comply with Title VI regulations forbidding funding recipients from ''restrict[ing] an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program'' or from ''utiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular race, color, or national origin.''

On that same day, DOJ issued a general guidance document addressed to ''Executive Agency Civil Rights Officers'' setting forth general principles for agencies to apply in developing guidance documents for recipients pursuant to the Executive Order. ''Enforcement of Title VI of the Civil Rights Act of 1964 National Origin Discrimination Against Persons With Limited English Proficiency,'' 65 FR 50123 (August 16, 2000) (''DOJ LEP Guidance'').

Subsequently, Federal agencies raised questions regarding the requirements of the Executive Order, especially in light of the Supreme Court's decision in *Alexander* v. *Sandoval.* On October 26, 2001, Ralph F. Boyd, Jr., Assistant Attorney General for the Civil Rights Division, issued a memorandum for ''Heads of Departments and Agencies, General Counsels and Civil Rights Directors.'' This memorandum clarified and reaffirmed the DOJ LEP Guidance in light of *Sandoval.*[3] The Assistant Attorney General stated that because *Sandoval* did not invalidate any Title VI regulations that proscribe conduct that has a disparate impact on covered groups—the types of regulations that form the legal basis for the part of Executive Order 13166 that applies to federally assisted programs and activities—the Executive Order remains in force. This Guidance is thus published pursuant to Executive Order 13166.

III. Who Is Covered?

Recipients of Federal financial assistance from Treasury are required to provide meaningful access to LEP persons.[4] Federal financial assistance includes grants, training, use of equipment, donations of surplus property, and other assistance. Recipients of assistance from Treasury typically include, but are not limited to, for example:

- Nonprofit organizations engaged in taxpayer education,
- Financial institutions serving distressed communities.

Subrecipients likewise are covered when Federal funds are passed through from one recipient to a subrecipient. This is true even if only one part of the recipient receives the Federal assistance.[5] Coverage extends to a recipient's entire program or activity; *i.e.,* to all parts of a recipient's operations.

Some recipients may operate in jurisdictions in which English has been declared the official language. Nonetheless, these recipients continue to be subject to Federal non-discrimination requirements, including those applicable to the provision of federally assisted services to persons with limited English proficiency.

IV. Who Is a Limited English Proficient Individual?

Individuals who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English can be limited English proficient, or ''LEP,'' entitled to language assistance with respect to a particular type of service, benefit, or encounter.

Examples of populations likely to include LEP persons who are encountered and/or served by Treasury's recipients and should be considered when planning language services include, but are not limited to:

- Persons participating in taxpayer education programs conducted by assisted non-profit organizations, and,
- Members of distressed communities seeking fiscal services from assisted financial institutions.

V. How Does a Recipient Determine the Extent of Its Obligation To Provide LEP Services?

Recipients are required to take reasonable steps to ensure meaningful access to their programs and activities by LEP persons. While designed to be a flexible and fact-dependent standard, the starting point is an individualized assessment that balances the following four factors: (1) The number or proportion of LEP persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the program to people's lives; and (4) the resources available to the grantee/recipient and costs. As indicated above, the intent of this guidance is to suggest a balance that ensures meaningful access by LEP persons to critical services while not imposing undue burdens on small business, small local governments, or small nonprofits.

After applying the above four-factor analysis, a recipient may conclude that different language assistance measures are sufficient for the different types of programs or activities in which it engages. For instance, some of a recipient's activities will be more important than others or have greater impact on or contact with LEP persons, and thus may require more in the way of language assistance. The flexibility that recipients have in addressing the needs of the LEP populations they serve does not diminish, and should not be used to minimize, the obligation that those needs be addressed. Treasury's

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[3] The memorandum noted that some commentators have interpreted *Sandoval* as impliedly striking down the disparate-impact regulations promulgated under Title VI that form the basis for the part of Executive Order 13166 that applies to federally assisted programs and activities. *See, e.g., Sandoval,* 532 U.S. at 286, 286 n.6 (''[W]e assume for purposes of this decision that section 602 confers the authority to promulgate disparate-impact regulations; * * * We cannot help observing, however, how strange it is to say that disparate-impact regulations are 'inspired by, at the service of, and inseparably intertwined with Sec. 601 * * * when Sec. 601 permits the very behavior that the regulations forbid.''). The memorandum, however, made clear that DOJ disagreed with the commentators' interpretation. *Sandoval* holds principally that there is no private right of action to enforce Title VI disparate-impact regulations. It did not address the validity of those regulations or Executive Order 13166 or otherwise limit the authority and responsibility of Federal grant agencies to enforce their own implementing regulations.

[4] Pursuant to Executive Order 13166, the meaningful access requirement of Title VI and the four-factor analysis set forth in the DOJ LEP Guidance are to additionally apply to the federally conducted programs and activities of federal agencies, including Treasury.

[5] However, if a Federal agency were to decide to terminate Federal funds based on noncompliance with Title VI, only funds directed to the particular program or activity that is out of compliance would be terminated. 41 U.S.C. 2000d–1.

recipients should apply the following four factors to the various kinds of contacts that they have with the public to assess language needs and decide what reasonable steps they should take to ensure meaningful access for LEP persons.

(1) The Number or Proportion of LEP Persons Served or Encountered in the Eligible Service Population

One factor in determining what language services recipients should provide is the number or proportion of LEP persons from a particular language group served or encountered in the eligible service population. The greater the number or proportion of these LEP persons, the more likely language services are needed. Ordinarily, persons ''eligible to be served, or likely to be directly affected, by'' a recipient's program or activity are those who are served or encountered in the eligible service population. This population will be program-specific, and includes persons who are in the geographic area that has been approved by a Federal grant agency as the recipient's service area. However, where, for instance, a precinct in the case of a law enforcement entity or a school in the case of an educational system serves a large LEP population, the appropriate service area is most likely the precinct or school, and not the entire population served by the recipient. Where no service area has previously been approved, the relevant service area may be that which is approved by State or local authorities or designated by the recipient itself, provided that these designations do not themselves discriminatorily exclude certain populations. When considering the number or proportion of LEP individuals in a service area, recipients providing educational services to minor LEP students should also include the students' LEP parent(s) or primary caretakers among those likely to be encountered.

Recipients should first examine their prior experiences with LEP encounters and determine the breadth and scope of language services that were needed. In conducting this analysis, it is important to include language minority populations that are eligible for their programs or activities but may be underserved because of existing language barriers. Other data should be consulted to refine or validate a recipient's prior experience, including the latest census data for the area served, data from school systems and from community organizations, and data from State and local governments.[6] Community agencies, school systems, religious organizations, legal aid entities, and others can often assist in identifying populations for whom outreach is needed and who would benefit from the recipients' programs and activities were language services provided.

(2) The Frequency With Which LEP Individuals Come in Contact With the Program

Recipients should assess, as accurately as possible, the frequency with which they have or should have contact with an LEP individual from different language groups seeking assistance. The more frequent the contact with a particular language group, the more likely that enhanced language services in that language are needed. The steps that are reasonable for a recipient that serves an LEP person on a one-time basis will be very different than those expected from a recipient that serves LEP persons daily.

It is also advisable to consider the frequency of different types of language contacts. For example, frequent contacts with Spanish-speaking people who are LEP may require certain assistance in Spanish. Less frequent contact with different language groups may suggest a different and less intensified solution. If an LEP individual accesses a program or service on a daily basis, a recipient has greater duties than if the same individual's program or activity contact is unpredictable or infrequent. But even recipients that serve LEP persons on an unpredictable or infrequent basis should use this balancing analysis to determine what to do if an LEP individual seeks services under the program in question. This plan need not be intricate. It may be as simple as being prepared to use one of the commercially-available telephonic interpretation services to obtain immediate interpreter services. In applying this standard, recipients should take care to consider whether appropriate outreach to LEP persons could increase the frequency of contact with LEP language groups.

[6] The focus of the analysis is on lack of English proficiency, not the ability to speak more than one language. Note that demographic data may indicate the most frequently spoken languages other than English and the percentage of people who speak that language who speak or understand English less than well. Some of the most commonly spoken languages other than English may be spoken by people who are also overwhelmingly proficient in English. Thus, they may not be the languages spoken most frequently by limited English proficient individuals. When using demographic data, it is important to focus in on the languages spoken by those who are not proficient in English.

(3) The Nature and Importance of the Program, Activity, or Service Provided by the Program

The more important the activity, information, service, or program, or the greater the possible consequences of the contact to the LEP individuals, the more likely language services are needed. For example, the obligations of a federally assisted school or hospital to LEP constituents are generally far greater than those of a federally assisted zoo or theater. A recipient needs to determine whether denial or delay of access to services or information could have serious or even life-threatening implications for the LEP individual. Decisions by a Federal, state, or local entity to make an activity compulsory, such as a particular educational program, can serve as strong evidence of the program's importance. While all situations must of course be analyzed on a case-by-case basis, the following general observations may be helpful to Treasury's recipients considering the implications of applying this factor of the four-factor test to their respective programs:

Examples

- An assisted financial institution in a city with a large Hispanic population including a significant number of LEP members should consider translating account and loan applications into Spanish (or implementing a procedure through which Spanish-speaking LEP persons could be served by Spanish-speaking officers).

With respect to the importance of a program, activity, or service provided by one of the Agency's recipients, the obligation to provide translation services will most likely be greatest in educational/training situations or in connection with the provision of law enforcement services. As an aid in applying this guidance to their own programs or activities, entities that receive Federal financial assistance from either the Department of Education or Department of Justice and Treasury may rely on the more particularized LEP Guidance of the Department of Education (in the case of a school-based educational program) or the Department of Justice (in the case of a law enforcement entity) to ensure compliance with the obligation to provide meaningful access in those respective contexts.

(4) The Resources Available to the Recipient and Costs

A recipient's level of resources and the costs that would be imposed on it may have an impact on the nature of the

steps it should take. Smaller recipients with more limited budgets are not expected to provide the same level of language services as larger recipients with larger budgets. In addition, ''reasonable steps'' may cease to be reasonable where the costs imposed substantially exceed the benefits.

Resource and cost issues, however, can often be reduced by technological advances; the sharing of language assistance materials and services among and between recipients, advocacy groups, and Federal grant agencies; and reasonable business practices. Where appropriate, training bilingual staff to act as interpreters and translators, information sharing through industry groups, telephonic and video conferencing interpretation services, pooling resources and standardizing documents to reduce translation needs, using qualified translators and interpreters to ensure that documents need not be ''fixed'' later and that inaccurate interpretations do not cause delay or other costs, centralizing interpreter and translator services to achieve economies of scale, or the formalized use of qualified community volunteers, for example, may help reduce costs.[7]

Recipients should carefully explore the most cost-effective means of delivering competent and accurate language services before limiting services due to resource concerns. Large entities and those entities serving a significant number or proportion of LEP persons should ensure that their resource limitations are well-substantiated before using this factor as a reason to limit language assistance. Such recipients may find it useful to be able to articulate, through documentation or in some other reasonable manner, their process for determining that language services would be limited based on resources or costs.

Treasury is well aware of the fact that some of its grant recipients may experience difficulties with resource allocation. Treasury emphasizes that reasonable translation and interpretation costs are appropriately included in grant and award budget requests.

This four-factor analysis necessarily implicates the ''mix'' of LEP services required. Recipients have two main ways to provide language services: Oral interpretation either in person or via telephone interpretation service (hereinafter ''interpretation'') and written translation (hereinafter ''translation''). Oral interpretation can range from on-site interpreters for critical services provided to a high volume of LEP persons to access through commercially-available telephonic interpretation services. Written translation, likewise, can range from translation of an entire document to translation of a short description of the document. In some cases, language services should be made available on an expedited basis while in others the LEP individual may be referred to another office of the recipient for language assistance.

The correct mix should be based on what is both necessary and reasonable in light of the four-factor analysis. Regardless of the type of language service provided, quality and accuracy of those services can be critical in order to avoid serious consequences to the LEP person and to the recipient. Recipients have substantial flexibility in determining the appropriate mix.

VI. Selecting Language Assistance Services

Recipients have two main ways to provide language services: Oral and written language services. Quality and accuracy of the language service is critical in order to avoid serious consequences to the LEP person and to the recipient.

A. Oral Language Services (Interpretation)

Interpretation is the act of listening to something in one language (source language) and orally translating it into another language (target language). Where interpretation is needed and is reasonable, recipients should consider some or all of the following options for providing competent interpreters in a timely manner:

• *Competence of Interpreters.* When providing oral assistance, recipients should ensure competency of the language service provider, no matter which of the strategies outlined below are used. Competency requires more than self-identification as bilingual. Some bilingual staff and community volunteers, for instance, may be able to communicate effectively in a different language when communicating information directly in that language, but not be competent to interpret in and out of English. Likewise, they may not be able to do written translations.

Competency to interpret, however, does not necessarily mean formal certification as an interpreter, although certification may be helpful. When using interpreters, recipients should ensure that they:

—Demonstrate proficiency in and ability to communicate information accurately in both English and in the other language and identify and employ the appropriate mode of interpreting (*e.g.*, consecutive, simultaneous, summarization, or sight translation);

—Have knowledge in both languages of any specialized terms or concepts peculiar to the entity's program or activity and of any particularized vocabulary and phraseology used by the LEP person;[8] and, if applicable, understand and follow confidentiality and impartiality rules to the same extent as the recipient employee for whom they are interpreting and/or to the extent their position requires.

—Understand and adhere to their role as interpreters without deviating into any other role such as counselor or advisor.

Some recipients may have additional self-imposed requirements for interpreters. Where individual rights depend on precise, complete, and accurate interpretation or translations, the use of certified interpreters is strongly encouraged. Where such proceedings are lengthy, the interpreter will likely need breaks and team interpreting may be appropriate to ensure accuracy and to prevent errors caused by mental fatigue of interpreters.

While quality and accuracy of language services is critical, the quality and accuracy of language services is nonetheless part of the appropriate mix of LEP services required. The quality and accuracy of language services in information about completion of tax forms, for example, must be quite high while the quality and accuracy of language services in translation of a brochure about the history of money need not meet the same exacting standards.

Finally, when interpretation is needed and is reasonable, it should be provided in a timely manner. To be meaningfully effective, language assistance should be timely. While there is no single definition for ''timely'' applicable to all

[7] Small recipients with limited resources may find that entering into a bulk telephonic interpretation service contract will prove cost effective.

[8] Many languages have ''regionalisms,'' or differences in usage. For instance, a word that may be understood to mean something in Spanish for someone from Cuba may not be so understood by someone from Mexico. In addition, because there may be languages which do not have an appropriate direct interpretation of some terms, the interpreter should be so aware and be able to provide the most appropriate interpretation. The interpreter should likely make the recipient aware of the issue and the interpreter and recipient can then work to develop a consistent and appropriate set of descriptions of these terms in that language that can be used again, when appropriate.

types of interactions at all times by all types of recipients, one clear guide is that the language assistance should be provided at a time and place that avoids the effective denial of the service, benefit, or right at issue or the imposition of an undue burden on or delay in important rights, benefits, or services to the LEP person. Conversely, where access to or exercise of a service, benefit, or right is not effectively precluded by a reasonable delay, language assistance can likely be delayed for a reasonable period.

—*Hiring Bilingual Staff.* When particular languages are encountered often, hiring bilingual staff offers one of the best, and often most economical, options. Recipients and sub-recipients can, for example, fill public contact positions with staff who are bilingual and competent to communicate directly with LEP persons in their language and at the appropriate level of competency. If bilingual staff are also used to interpret between English speakers and LEP persons, or to orally interpret written documents from English into another language, they should be competent in the skill of interpreting. Being bilingual does not necessarily mean that a person has the ability to interpret. In addition, there may be times when the role of the bilingual employee may conflict with the role of an interpreter (for instance, a bilingual member of a formal review panel adjudicating allegations of program or fiscal noncompliance would probably not be able to perform effectively the role of interpreter and adjudicator at the same time, even if the bilingual employee were a qualified interpreter). Effective management strategies, including any appropriate adjustments in assignments and protocols for using bilingual staff, can ensure that bilingual staff are fully and appropriately utilized. When bilingual staff cannot meet all of the language service obligations of the recipient, the recipient should turn to other options.

—*Hiring Staff Interpreters.* Hiring interpreters may be most helpful where there is a frequent need for interpreting services in one or more languages. Depending on the facts, sometimes it may be necessary and reasonable to provide on-site interpreters to provide accurate and meaningful communication with an LEP person.

—*Contracting for Interpreters.* Contract interpreters may be a cost-effective option when there is no regular need for a particular language skill. In addition to commercial and other private providers, many community-based organizations and mutual assistance associations provide interpretation services for particular languages. Contracting with and providing training regarding the recipient's programs and processes to these organizations can be a cost-effective option for providing language services to LEP persons from those language groups.

—*Using Telephone Interpreter Lines.* While of limited value for live performances or museum exhibits, telephone interpreter service lines often offer speedy interpreting assistance in many different languages in other public-contact situations. They may be particularly appropriate where the mode of communicating with an English proficient person would also be over the phone. Although telephonic interpretation services are useful in many situations, it is important to ensure that, when using such services, the interpreters used are competent to interpret any technical terms specific to a particular program that may be important parts of the conversation. Nuances in language and non-verbal communication can often assist an interpreter and cannot be recognized over the phone. Video teleconferencing may sometimes help to resolve this issue where necessary. In addition, where documents are being discussed, it is important to give telephonic interpreters adequate opportunity to review the document prior to the discussion and any logistical problems should be addressed.

—*Using Community Volunteers.* In addition to consideration of bilingual staff, staff interpreters, or contract interpreters (either in-person or by telephone) as options to ensure meaningful access by LEP persons, use of recipient-coordinated community volunteers, working with, for instance, community-based organizations may provide a cost-effective supplemental language assistance strategy under appropriate circumstances. They may be particularly useful in providing language access for a recipient's less critical programs and activities. To the extent the recipient relies on community volunteers, it is often best to use volunteers who are trained in the information or services of the program and can communicate directly with LEP persons in their language. Just as with all interpreters, community volunteers used to interpret between English speakers and LEP persons, or to orally translate documents, should be competent in the skill of interpreting and knowledgeable about applicable confidentiality and impartiality rules, if any. Recipients should consider formal arrangements with community-based organizations that provide volunteers to address these concerns and to help ensure that services are available more regularly.

—*Use of Family Members or Friends as Interpreters.* Although recipients should not plan to rely on an LEP person's family members, friends, or other informal interpreters to provide meaningful access to important programs and activities, where LEP persons so desire, they should be permitted to use, at their own expense, an interpreter of their own choosing (whether a professional interpreter, family member, or friend) in place of or as a supplement to the free language services expressly offered by the recipient. LEP persons may feel more comfortable when a trusted family member or friend acts as an interpreter. In addition, in exigent circumstances that are not reasonably foreseeable, temporary use of interpreters not provided by the recipient may be necessary. However, with proper planning and implementation, recipients should be able to avoid most such situations. Recipients, however, should take special care to ensure that family, legal guardians, caretakers, and other informal interpreters are appropriate in light of the circumstances and subject matter of the program, service or activity, including protection of the recipient's own administrative or enforcement interest in accurate interpretation. In many circumstances, family members (especially children) or friends are not competent to provide quality and accurate interpretations. Issues of confidentiality, privacy, or conflict of interest may also arise. LEP individuals may feel uncomfortable revealing or describing sensitive, confidential, or potentially embarrassing information to a family member, friend, or member of the local community. In addition, such informal interpreters may have a personal connection to the LEP person or an undisclosed conflict of interest. For these reasons, when oral language services are necessary, recipients should generally offer competent interpreter services free of cost to the LEP person.

While issues of competency, confidentiality, and conflict of interest in the use of family members or friends often make their use inappropriate, the

use of these individuals as interpreters may be an appropriate option where proper application of the four factors would lead to a conclusion that recipient-provided services are not necessary. If the importance and nature of the activity is relatively low and unlikely to implicate issues of confidentiality, conflict of interest, or the need for accuracy, and the resources needed and costs of providing language services are high, an LEP person's use of family, friends, or others may be appropriate.

If the LEP person voluntarily chooses to provide his or her own interpreter, a recipient should consider whether a record of that choice and of the recipient's offer of assistance is appropriate. Where precise, complete, and accurate interpretations or translations of information and/or testimony are critical, or where the competency of the LEP person's interpreter is not established, a recipient might decide to provide its own, independent interpreter, even if an LEP person wants to use his or her own interpreter as well. Extra caution should be exercised when the LEP person chooses to use a minor as the interpreter. While the LEP person's decision should be respected, there may be additional issues of competency, confidentiality, or conflict of interest when the choice involves using children as interpreters. The recipient should take care to ensure that the LEP person's choice is voluntary, that the LEP person is aware of the possible problems if the preferred interpreter is a minor child, and that the LEP person knows that a competent interpreter could be provided by the recipient at no cost.

B. Written Language Services (Translation)

Translation is the replacement of a written text from one language (source language) into an equivalent written text in another language (target language).

What Documents Should be Translated? After applying the four-factor analysis, a recipient may determine that an effective LEP plan for its particular program or activity includes the translation of vital written materials into the language of each frequently-encountered LEP group eligible to be served and/or likely to be affected by the recipient's program.

Such written materials could include, for example:

—Notices advising LEP persons of free language assistance
—Written tests that do not assess English language competency, but test competency for a particular license, job, or skill for which knowing English is not required
—Applications to participate in a recipient's program or activity or to receive recipient benefits, grants, or services.

Whether or not a document (or the information it solicits) is ''vital'' may depend upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner. Where appropriate, recipients are encouraged to create a plan for consistently determining, over time and across its various activities, what documents are ''vital'' to the meaningful access of the LEP populations they serve.

Classifying a document as vital or non-vital is sometimes difficult, especially in the case of outreach materials like brochures or other information on rights and services. Awareness of rights or services is an important part of ''meaningful access.'' Lack of awareness that a particular program, right, or service exists may effectively deny LEP individuals meaningful access. Thus, where a recipient is engaged in community outreach activities in furtherance of its activities, it should regularly assess the needs of the populations frequently encountered or affected by the program or activity to determine whether certain critical outreach materials should be translated. Community organizations may be helpful in determining what outreach materials may be most helpful to translate. In addition, the recipient should consider whether translations of outreach material may be made more effective when done in tandem with other outreach methods, including utilizing the ethnic media, schools, religious, and community organizations to spread a message.

Sometimes a document includes both vital and non-vital information. This may be the case when the document is very large. It may also be the case when the title and a phone number for obtaining more information on the contents of the document in frequently-encountered languages other than English is critical, but the document is sent out to the general public and cannot reasonably be translated into many languages. Thus, vital information may include, for instance, the provision of information in appropriate languages other than English regarding where a LEP person might obtain an interpretation or translation of the document.

Into What Languages Should Documents be Translated? The languages spoken by the LEP individuals with whom the recipient has contact determine the languages into which vital documents should be translated. A distinction should be made, however, between languages that are frequently encountered by a recipient and less commonly-encountered languages. Many recipients serve communities in large cities or across the country. They regularly serve LEP persons who speak dozens and sometimes over 100 different languages. To translate all written materials into all of those languages is unrealistic. Although recent technological advances have made it easier for recipients to store and share translated documents, such an undertaking would incur substantial costs and require substantial resources. Nevertheless, well-substantiated claims of lack of resources to translate all vital documents into dozens of languages do not necessarily relieve the recipient of the obligation to translate those documents into at least several of the more frequently-encountered languages and to set benchmarks for continued translations into the remaining languages over time. As a result, the extent of the recipient's obligation to provide written translations of documents should be determined by the recipient on a case-by-case basis, looking at the totality of the circumstances in light of the four-factor analysis. Because translation is a one-time expense, consideration should be given to whether the up-front cost of translating a document (as opposed to oral interpretation) should be amortized over the likely lifespan of the document when applying this four-factor analysis.

Safe Harbor. Many recipients would like to ensure with greater certainty that they comply with their obligations to provide written translations in languages other than English. Paragraphs (a) and (b) outline the circumstances that can provide a ''safe harbor'' for recipients regarding the requirements for translation of written materials. A ''safe harbor'' means that if a recipient provides written translations under these circumstances, such action will be considered strong evidence of compliance with the recipient's written-translation obligations.

The failure to provide written translations under the circumstances outlined in paragraphs (a) and (b) does not mean there is non-compliance. Rather, they provide a common starting point for recipients to consider whether and at what point the importance of the service, benefit, or activity involved; the nature of the information sought; and the number or proportion of LEP persons served call for written

translations of commonly-used forms into frequently-encountered languages other than English. Thus, these paragraphs merely provide a guide for recipients that would like greater certainty of compliance than can be provided by a fact-intensive, four-factor analysis.

Example: Even if the safe harbors are not used, if written translation of a certain document(s) would be so burdensome as to defeat the legitimate objectives of its program, the translation of the written materials is not necessary. Other ways of providing meaningful access, such as effective oral interpretation of certain vital documents, might be acceptable under such circumstances.

Safe Harbor Guides. The following actions will be considered strong evidence of compliance with the recipient's written-translation obligations:

(a) The recipient provides written translations of vital documents for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other documents, if needed, can be provided orally; or

(b) If there are fewer than 50 persons in a language group that reaches the five percent trigger in (a), the recipient does not translate vital written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those written materials, free of cost.

These safe harbor provisions apply to the translation of written documents only. They do not affect the requirement to provide meaningful access to LEP individuals through competent oral interpreters where oral language services are needed and are reasonable.

Treasury provides assistance to a range of programs and activities serving different geographic areas with varying populations. Moreover, as noted above, the obligation to consider translations applies only to a recipient's vital documents having a significant impact on access rather than all types of documents used or generated by a recipient in the course of its activities. For these reasons, a strict reliance on the numbers or percentages set out in the safe harbor standards may not be appropriate for all of Treasury's recipients and for all their respective programs or activities. While the safe harbor standards outlined above offer a common guide, the decision as to what documents should be translated should ultimately be governed by the underlying obligation under Title VI to provide meaningful access by LEP persons by ensuring that the lack of appropriate translations of vital documents does not adversely impact upon an otherwise eligible LEP persons ability to access its programs or activities.

Competence of Translators. As with oral interpreters, translators of written documents should be competent. Many of the same considerations apply. However, the skill of translating is very different from the skill of interpreting, and a person who is a competent interpreter may or may not be competent to translate.

Particularly where vital documents are being translated, competence can often be achieved by use of certified translators. Certification or accreditation may not always be possible or necessary.[9] Competence can often be ensured by having a second, independent translator ''check'' the work of the primary translator. Alternatively, one translator can translate the document, and a second, independent translator could translate it back into English to check that the appropriate meaning has been conveyed. This is called ''back translation.''

Translators should understand the expected reading level of the audience and, where appropriate, have fundamental knowledge about the target language group's vocabulary and phraseology. Sometimes direct translation of materials results in a translation that is written at a much more difficult level than the English language version or has no relevant equivalent meaning.[10] Community organizations may be able to help consider whether a document is written at a good level for the audience. Likewise, consistency in the words and phrases used to translate terms of art or other technical concepts helps avoid confusion by LEP individuals and may reduce costs. Creating or using already-created glossaries of commonly-used terms may be useful for LEP persons and translators and cost effective for the recipient. Providing translators with examples of previous accurate translations of similar material by the recipient, other recipients, or Federal agencies may be helpful.

While quality and accuracy of translation services is critical, the quality and accuracy of translation services is nonetheless part of the appropriate mix of LEP services required. For instance, documents that are simple and have no significant consequence for LEP persons who rely on them may use translators that are less skilled than important documents with legal or other information upon which reliance has important consequences. The permanent nature of written translations, however, imposes additional responsibility on the recipient to ensure that the quality and accuracy permit meaningful access by LEP persons.

VII. Elements of Effective Plan on Language Assistance for LEP Persons

After completing the four-factor analysis and deciding what language assistance services are appropriate, a recipient should develop an implementation plan to address the identified needs of the LEP populations they serve. Recipients have considerable flexibility in developing this plan. The development and maintenance of a periodically-updated written plan on language assistance for LEP persons (''LEP plan'') for use by recipient employees serving the public will likely be the most appropriate and cost-effective means of documenting compliance and providing a framework for the provision of timely and reasonable language assistance. Moreover, such written plans would likely provide additional benefits to a recipient's managers in the areas of training, administration, planning, and budgeting. These benefits should lead most recipients to document in a written LEP plan their language assistance services, and how staff and LEP persons can access those services. Despite these benefits, certain recipients, such as recipients serving very few LEP persons and recipients with very limited resources, may choose not to develop a written LEP plan. However, the absence of a written LEP plan does not obviate the underlying obligation to ensure meaningful access by LEP persons to a recipient's program

[9] For those languages in which no formal accreditation currently exists, a particular level of membership in a professional translation association can provide some indicator of professionalism.

[10] For instance, there may be languages which do not have an appropriate direct translation of some terms and the translator should be able to provide an appropriate translation. The translator should likely also make the recipient aware of this. Recipients can then work with translators to develop a consistent and appropriate set of descriptions of these terms in that language that can be used again, when appropriate. Recipients will find it more effective and less costly if they try to maintain consistency in the words and phrases used to translate terms of art and legal or other technical concepts. Creating or using already-created glossaries of commonly used terms may be useful for LEP persons and translators and cost effective for the recipient. Providing translators with examples of previous translations of similar material by the recipient, other recipients, or federal agencies may be helpful.

or activities. Accordingly, in the event that a recipient elects not to develop a written plan, it should consider alternative ways to articulate in some other reasonable manner a plan for providing meaningful access. Entities having significant contact with LEP persons, such as schools, religious organizations, community groups, and groups working with new immigrants can be very helpful in providing important input into this planning process from the beginning.

The following five steps may be helpful in designing an LEP plan and are typically part of effective implementation plans.

(1) Identifying LEP Individuals Who Need Language Assistance

The first two factors in the four-factor analysis require an assessment of the number or proportion of LEP individuals eligible to be served or encountered and the frequency of encounters. This requires recipients to identify LEP persons with whom it has contact. One way to determine the language of communication is to use language identification cards (or ''I speak cards''), which invite LEP persons to identify their language needs to staff. Such cards, for instance, might say ''I speak Spanish'' in both Spanish and English, ''I speak Vietnamese'' in both English and Vietnamese, etc. To reduce costs of compliance, the federal government has made a set of these cards available on the Internet. The Census Bureau ''I speak card'' can be found and downloaded at *http://www.usdoj.gov/crt/cor/13166.htm.* When records are normally kept of past interactions with members of the public, the language of the LEP person can be included as part of the record. In addition to helping employees identify the language of LEP persons they encounter, this process will help in future applications of the first two factors of the four-factor analysis. In addition, posting notices in commonly encountered languages notifying LEP persons of language assistance will encourage them to self-identify.

(2) Language Assistance Measures

An effective LEP plan would likely include information about the ways in which language assistance will be provided. For instance, recipients may want to include information on at least the following:

— Types of language services available.
— How staff can obtain those services.
— How to respond to LEP callers.
— How to respond to written communications from LEP persons.
— How to respond to LEP individuals who have in-person contact with recipient staff.
— How to ensure competency of interpreters and translation services.

(3) Training Staff

Staff should know their obligations to provide meaningful access to information and services for LEP persons. An effective LEP plan would likely include training to ensure that:

— Staff know about LEP policies and procedures.
— Staff having contact with the public are trained to work effectively with in-person and telephone interpreters.

Recipients may want to include this training as part of the orientation for new employees. It is important to ensure that all employees in public contact positions are properly trained. Recipients have flexibility in deciding the manner in which the training is provided. The more frequent the contact with LEP persons, the greater the need will be for in-depth training. Staff with little or no contact with LEP persons may only have to be aware of an LEP plan. However, management staff, even if they do not interact regularly with LEP persons, should be fully aware of and understand the plan so they can reinforce its importance and ensure its implementation by staff.

(4) Providing Notice to LEP Persons

Once an organization has decided, based on the four factors, that it will provide language services, it is important for the recipient to let LEP persons know that those services are available and that they are free of charge. Recipients should provide this notice in a language LEP persons will understand. Examples of notification that recipients should consider include: Posting signs in intake areas and other entry points. When language assistance is needed to ensure meaningful access to information and services, it is important to provide notice in appropriate languages in intake areas or initial points of contact so that LEP persons can learn how to access those language services. For instance, signs in intake offices could state that free language assistance is available. The signs should be translated into the most common languages encountered. They should explain how to get the language help.[11]

— Stating in outreach documents that language services are available from the agency. Announcements could be in, for instance, brochures, booklets, and in outreach and recruitment information. These statements should be translated into the most common languages and could be ''tagged'' onto the front of common documents.
— Working with community-based organizations and other stakeholders to inform LEP individuals of the recipients' services, including the availability of language assistance services.
— Using a telephone voice mail menu. The menu could be in the most common languages encountered. It should provide information about available language assistance services and how to get them.
— Including notices in local newspapers in languages other than English.
— Providing notices on non-English-language radio and television stations about the available language assistance services and how to get them.
— Presentations and/or notices at schools and religious organizations.

(5) Monitoring and Updating the LEP Plan

Recipients should, where appropriate, have a process for determining, on an ongoing basis, whether new documents, programs, services, and activities need to be made accessible for LEP individuals, and they may want to provide notice of any changes in services to the LEP public and to employees. In addition, recipients should consider whether changes in demographics, types of services, or other needs require annual reevaluation of their LEP plan. Less frequent reevaluation may be more appropriate where demographics, services, and needs are more static. One good way to evaluate the LEP plan is to seek feedback from the community.

In their reviews, recipients may want to consider assessing changes in:

— Current LEP populations in service area or population affected or encountered.
— Frequency of encounters with LEP language groups.

• Nature and importance of activities to LEP persons.

• Availability of resources, including technological advances and sources of additional resources, and the costs imposed.

• Whether existing assistance is meeting the needs of LEP persons.

• Whether staff knows and understands the LEP plan and how to implement it.

[11] The Social Security Administration has made such signs available at *http://www.ssa.gov/multilanguage/langlist1.htm*. These signs could, for example, be modified for recipient use.

• Whether identified sources for assistance are still available and viable.

In addition to these five elements, effective plans set clear goals, management accountability, and opportunities for community input and planning throughout the process.

VIII. Voluntary Compliance Effort

The goal for Title VI and Title VI regulatory enforcement is to achieve voluntary compliance. The requirement to provide meaningful access to LEP persons is implemented by Treasury through complaint investigations, compliance reviews, efforts to secure voluntary compliance, and technical assistance. Upon publication of Treasury's Title VI regulations, the enforcement procedures in those regulations will be applicable to this program.

Treasury will investigate whenever it receives a complaint, report, or other information that alleges or indicates possible noncompliance with Title VI. If the investigation results in a finding of compliance, Treasury will inform the recipient in writing of this determination, including the basis for the determination. Treasury will use voluntary mediation to resolve most complaints. However, if a case is fully investigated and results in a finding of noncompliance, Treasury will inform the recipient of the noncompliance through a Letter of Findings that sets out the areas of noncompliance and the steps that must be taken to correct the noncompliance. It will first attempt to secure voluntary compliance through informal means. If the matter cannot be resolved informally, Treasury will secure compliance through the termination of federal assistance after the recipient has been given an opportunity for an administrative hearing and/or by referring the matter to a DOJ litigation section to seek injunctive relief or pursue other enforcement proceedings. Treasury will engage in voluntary compliance efforts and provide technical assistance to recipients at all stages of an investigation. During these efforts, Treasury will propose reasonable timetables for achieving compliance and consult with and assist recipients in exploring cost-effective ways of coming into compliance. In determining a recipient's compliance with the Title VI regulations, Treasury's primary concern is to ensure that the recipient's policies and procedures provide meaningful access for LEP persons to the recipient's programs and activities.

While all recipients must work toward building systems that will ensure access for LEP individuals, Treasury acknowledges that the implementation of a comprehensive system to serve LEP individuals is a process and that a system will evolve over time as it is implemented and periodically reevaluated. As recipients take reasonable steps to provide meaningful access to federally assisted programs and activities for LEP persons, Treasury will look favorably on intermediate steps recipients take that are consistent with this Guidance, and that, as part of a broader implementation plan or schedule, move their service delivery system toward providing full access to LEP persons. This does not excuse noncompliance but instead recognizes that full compliance in all areas of a recipient's activities and for all potential language minority groups may reasonably require a series of implementing actions over a period of time. However, in developing any phased implementation schedule, recipients should ensure that the provision of appropriate assistance for significant LEP populations or with respect to activities having a significant impact on the health, safety, legal rights, or livelihood of beneficiaries is addressed first. Recipients are encouraged to document their efforts to provide LEP persons with meaningful access to federally assisted programs and activities.

In cases where a recipient of Federal financial assistance from Treasury also receives assistance from one or more other Federal agencies, there is no obligation to conduct and document separate but identical analyses and language assistance plans. Treasury, in discharging its compliance and enforcement obligations under Title VI, will look to analyses performed and plans developed in response to similar detailed LEP guidance issued by other Federal agencies. Accordingly, as an adjunct to this Guidance, recipients may, where appropriate, also rely on guidance issued by other agencies in discharging their Title VI LEP obligations.

In determining a recipient entity's compliance with Title VI, Treasury's primary concern is to ensure that the entity's policies and procedures overcome barriers resulting from language differences that would deny LEP persons a meaningful opportunity to participate in and access programs, services, and benefits. A recipient entity's appropriate use of the methods and options discussed in this policy guidance is viewed by Treasury as evidence of that entity's willingness to comply voluntarily with its Title VI obligations.

IX. Complaint Process

Anyone who believes that he/she has been discriminated against because of race, color or national origin in violation of Title VI may file a complaint with Treasury within 180 days of the date on which the discrimination took place.

The following information should be included:

• Your name and address (a telephone number where you may be reached during business hours is helpful, but not required);

• A general description of the person(s) or class of persons injured by the alleged discriminatory act(s);

• The name and location of the organization or institution that committed the alleged discriminatory act(s);

• A description of the alleged discriminatory act(s) in sufficient detail to enable the Office of Equal Opportunity and Diversity (OEOD) to understand what occurred, when it occurred, and the basis for the alleged discrimination.

• The letter or form must be signed and dated by the complainant or by someone authorized to do so on his or her behalf.

A recipient may not retaliate against any person who has made a complaint, testified, assisted or participated in any manner in an investigation or proceeding under the statutes governing Federal financial assistance programs.

Civil rights complaints should be filed with: Department of the Treasury, Office of Equal Opportunity and Diversity, 1750 Pennsylvania Avenue, NW., Room 8157, Washington, DC 20220.

[FR Doc. 05–2156 Filed 2–3–05; 8:45 am]

BILLING CODE 4811–15–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0501]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register**

concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to maintain Veterans Mortgage Life Insurance accounts.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before April 5, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20m35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0501'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501 ''3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Veterans Mortgage Life Insurance Inquiry, VA Form 29–0543.

OMB Control Number: 2900–0501.

Type of Review: Extension of a currently approved collection.

Abstract: Veterans whose mortgage is insured under Veterans Mortgage Life Insurance (VMLI) completes VA Form 29–0543 to report any recent changes in the status of their mortgage. VMLI coverage is automatically terminated when the mortgage is paid in full or when the title to the property secured by the mortgage is no longer in the veteran's name.

Affected Public: Individuals or households.

Estimated Annual Burden: 45 hours.

Estimated Average Burden Per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 540.

Dated: January 26, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–2105 Filed 2–3–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0115]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine eligibility for benefits based on a common law marriage.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before April 5, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0115'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C., 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Supporting Statement Regarding Marriage, VA Form 21–4171.

OMB Control Number: 2900–0115.

Type of Review: Extension of a currently approved collection.

Abstract: The data collected on VA Form 21–4172 is used to determine a claimant's eligibility for benefits based on a common law marital relationship. Benefits cannot be paid unless the marital relationship between the claimant and the veteran is established.

Affected Public: Individuals or households.

Estimated Annual Burden: 800 hours.

Estimated Average Burden Per Respondent: 20 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 2,400.

Dated: January 26, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–2106 Filed 2–3–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0405]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the

Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to confirm a claimant's continued entitlement to Restored Entitlement Program for Survivors (REPS) benefits.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before April 5, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0405'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Public Law 104–13; 44 U.S.C. 3501—3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: REPS Annual Eligibility Report, (Under the Provisions of Section 156, Public Law 97–377), VA Form 21–8941.

OMB Control Number: 2900–0405.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 21–8941 is completed annually by claimants who have earned income that is at or near the limit of earned income. The REPS program pays benefits to certain surviving spouses and children of veterans who died or disabled in service prior to August 13, 1981 or who died as a result of a service-connected disability incurred or aggravated prior to August 12, 1981. VA uses the information collected to determine a claimant's continued entitlement to REPS benefits.

Affected Public: Individuals or households.

Estimated Annual Burden: 300 hours.

Estimated Average Burden Per Respondent: 15 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 1,200.

Dated: January 26, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–2157 Filed 2–3–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0216]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine the appropriate claimant entitlement to accrued benefits.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before April 5, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0216'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Public Law 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Application for Reimbursement from Accrued Amounts Due a Deceased Beneficiary, VA Form 21–601.

OMB Control Number: 2900–0216.

Type of Review: Revision of a currently approved collection.

Abstract: The information collected on VA Form 21–601 is use to determine claimants entitlement to accrued benefits due a veteran but not paid prior to the veteran's death. Each survivor claiming a share of the accrued benefits must complete a separate VA Form 21–601; however if there is no living survivors who are entitled on the basis of relationship, accrued benefits may be payable as reimbursement to the person or persons who bore the expenses of the veteran's last illness and burial expenses.

Affected Public: Individuals or households and Business or other for-profit.

Estimated Annual Burden: 2,300 hours.

Estimated Average Burden Per Respondent: 30 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 4,600.

Dated: January 26, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–2158 Filed 2–3–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Office of Research and Development; Government Owned Invention Available for Licensing

AGENCY: Office of Research and Development, VA.

ACTION: Notice of government owned invention available for licensing.

SUMMARY: The invention listed below is owned by the U.S. Government as represented by the Department of Veterans Affairs, and is available for licensing in accordance with 35 U.S.C. 207 and 37 CFR part 404 and/or CRADA Collaboration under 15 U.S.C. 3710a to achieve expeditious commercialization of results of federally funded research and development. Foreign patents are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Technical and licensing information on the invention may be obtained by writing to: Sal Sheredos, Department of Veterans Affairs, Acting Director Technology Transfer Program, Office of Research and Development, 810 Vermont Avenue, NW., Washington, DC 20420; fax: (202) 254–0473; e-mail at: *saleem@vard.org.* Any request for information should include the Number and Title for the relevant invention as indicated below. Issued patents may be obtained from the Commissioner of Patents, U.S. Patent and Trademark Office, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: The invention available for licensing is: U.S. Provisional Patent Application No. 60/600,797 ''Human and Mouse Alkaline Ceramidase 1 and Skin Disease''.

Dated: January 26, 2005.

Anthony J. Principi,

Secretary, Department of Veterans Affairs.

[FR Doc. 05–2108 Filed 2–3–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; Systems of Records

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, 5 U.S.C. 552a(e), the Department of Veterans Affairs (VA) is publishing notice of amendment and alteration to its system of records known as ''Veterans Appellate Records System-VA (44VA01),'' and ''Representatives'' Fee Agreement Records System (81VA01).'' VA is merging the information currently maintained in Representatives' Fee Agreement Records with the ''Veterans Appellate Records System.'' The amendments will affect the sections entitled System Location; Categories of Individuals Covered by the System; Categories of Records in the System; Purpose(s); Routine Uses of Records Maintained in the System; and Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records in the System. VA is publishing the combined system notice in its entirety at this time.

DATES: Comments must be received by VA on or before March 7, 2005, which is the date the amended system will become effective.

ADDRESSES: Mail or hand-deliver written comments to: Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Room 1068, Washington, DC 20420; or fax comments to (202) 273–9026; or e-mail comments to *VAregulations@mail.va.gov*. Comments should indicate that they are submitted in response to the Notice of Amendments to a System of Records. All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call 202 273–9515 for an appointment.

FOR FURTHER INFORMATION CONTACT: Steven L. Keller, Senior Deputy Vice Chairman, Board of Veterans' Appeals (012), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 565–5978.

SUPPLEMENTARY INFORMATION: The Veterans Appellate Records System (44VA01) was first established in 1975 to track claims for veterans benefits that had been appealed to the Board of Veterans' Appeals (BVA or Board). With the expansion of advanced technology and increased electronic data collection capacity, traditional methods of recordkeeping have changed significantly. BVA now maintains most of the records covered by 44VA01 in a computer database entitled Veterans Appeals Control and Locator System (VACOLS).

One of the traditional paper-based methods of keeping track of appeals at the Board was use of the Briefface folder. These Briefface folders traditionally reflected the status of the appeal as it traveled through the Board until an appeal was decided. Thereafter, the Briefface was removed from the claims folder before the folder was returned to the VA Regional Office (VARO). The Briefface remained at BVA as a document in system 44VA01 until disposed of in accordance with procedures approved by the Archivist of the United States. However, since all the information contained in the Briefface is now tracked electronically, the Briefface is obsolete. Therefore, the Board is discontinuing this method of collecting data. Brieffaces in use as of March 31, 2002, will be maintained in an offsite storage facility once the Board has decided an appeal. They will be disposed of by shredding or burning after 18 months according to the timeline and procedural requirements of General Records Schedule 16, Item 7.

The Representatives' Fee Agreement Records System—VA , identified as 81VA01, was established in 1991 to allow the Board to monitor fee agreements between attorneys-at-law or accredited agents and claimants being represented before VA according to the provisions of 38 U.S.C. 5904. The information contained in this system includes paper copies of fee agreements and correspondence related to fee agreements and electronic information with regard to names and addresses of both parties to the agreements and VA identification numbers or social security numbers. Since most of this information is already contained in VACOLS (44VA01), we believe that merging the two systems will obviate the need to retain 81VA01 and will eliminate redundant data entry.

In addition, providing the information through VACOLS allows a VARO to locate any existing fee agreement that requires withholding of a portion of the payment of past due benefits to a beneficiary. As of April 1, 2003, fee agreements and powers of attorney received by the Board have been scanned and electronically available in VACOLS. Thus, VARO personnel no longer need to contact the Board in every instance where the question of fee agreements arises and the Board need not create paper file folders to hold duplicate copies of fee agreements. The original fee agreement remains in the claimant's file folder and the electronically attached copy along with other pertinent data, becomes part of VACOLS.

The System Location notice has been updated to reflect the locations of the computer servers that house the system as well as VA sites where non-electronic records (*e.g.*, tapes of hearings) are housed, as well as the address of the Board's contractor.

The section, Categories of Individuals Covered by the System, refers to the persons by whose names records may be retrieved from the system. The notice has been amended to remove categories of individuals on whom information may be stored in VACOLS, but which cannot be retrieved by the individual's name or other personal identifier.

The Categories of Records section in the system notice has been expanded to reflect the addition of information pertaining to contesting parties, agents, and private attorneys; to include digital recordings of hearings, copies of written fee agreements and documents relating to the filing and review of fee agreements; procedural information on the disposition of claims where a Board decision has been remanded from or overturned by the United States Court of Appeals for Veterans Claims; and to describe more fully the older, non-electronic records in the system.

The Purpose statement has been amended to include the monitoring of attorney fee agreements, statistical evaluation of the appellate process and evaluation of employee performance.

VA proposes to add five new routine uses and rewrite and consolidate existing ones. Because this system contains material relating to employee evaluations, four of these will permit release of information to the Merit Systems Protection Board, the Equal Employment Opportunity Commission, the Federal Labor Relations Authority and the employee's union. Permission to release information from this system to law enforcement personnel and security guards has been clarified, indicating that release is permitted in order to alert them to the presence of dangerous persons in VA facilities or at VA activities conducted in non-VA facilities. The routine use permitting release of information regarding the legality or ethical propriety of representatives has been expanded to permit release to other Federal and State agencies and to Federal courts. The remaining new routine use is carried over from system 81VA01 and permits release of attorney fee information to the United States Court of Appeals for Veterans Claims when an order of the Board has been applied to that Court in accordance with the provisions of 38 U.S.C. 5904(c)(2).

The Storage portion of the notice has been amended to reflect changes in the nature of records kept. Verbatim recordings of hearings, previously recorded on magnetic tape will be recorded and stored digitally until a transcript has been made and electronically attached in VACOLS. According to Rule 714 of the Board's Rules of Practice, 38 CFR 20.714, when a transcript of a hearing is made, the transcript becomes the official record of the hearing and the recording is retained as a duplicate record of the hearing for 12 months, after which time it is destroyed according to NARA approved standards. With the change from audio to digital recordings and the practice of creating a transcript of all hearings, destruction of hearing recordings will follow procedures to be established in revisions to Rule 714 of the Board of Veterans' Appeals Rules of Practice, 38 CFR 20.714, that will permit challenge to the accuracy of the transcription prior to destruction of the recording.

The Retrievability section has been amended to note that information from this system that is stored in VACOLS can now be retrieved by any searchable field in the VACOLS program. However, this system notice covers only information retrieved by an individual's name or other personal identifier. Retrievability of archived materials not stored in VACOLS is unchanged except that attorney fee agreements and related correspondence received prior to the practice of incorporating them in VACOLS and kept in file folders may be retrieved by the name of the appellant.

The Privacy Act, 5 U.S.C. 552a(b)(1) provides that agencies may disclose records contained in a system of records ''to those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties.'' The Safeguards statement currently provides that records in this system ''are under custody of designated employees with access only to employees of the Board of Veterans' Appeals and its contractor who needs to know.'' It has become advisable for Department of Veterans Affairs Regional Office (VARO) employees to be able to follow the progress of appeals and answer veteran and other appellant questions on the process. More appellants file multiple and concurrent appeals for a variety of issues than ever before. Because BVA may or may not already have made a decision on any one of these appeals, and because of the increasing numbers of these multiple and concurrent actions, it is in the best interest of the VAROs to have an electronic indicator of what actions have taken place. Therefore it has become necessary to expand the population of employees with access to VACOLS to include employees of the VA Compensation and Pension Service (C&P) and VAROs. VACOLS can be set to automatically limit the access of individuals to specified records. Designated VARO and C&P employees are able to view any records in VACOLS so that they can respond to inquiries from appellants, representatives and Members of Congress. Designated employees of the VARO where an appeal originates have the ability to modify electronic records based on the status of the appeal. For example, if an appeal is in advance status (ADV), the appeal is in the process of being developed and the VARO can modify any part of the electronic record. When a claim has been certified to the Board on appeal and the file has been received at the Board, its status is converted to active (ACT). When a case is in ACT status, VARO employees cannot modify any part of the VACOLS record. This is also true when a case is in remand (REM) status or after the Board enters a final decision and the file goes into history (HIS) status.

VACOLS is available to authorized persons through the VA wide area network (WAN), which means that access is limited to those who are actually in VA buildings, ROs, Medical Centers, etc. Because 38 U.S.C. 5902 and 38 CFR 14.635 permit VA to provide office space to Veterans Service Organizations (VSOs), it is possible to provide representatives of those organizations who work in VA buildings with limited access to VACOLS if they have a valid, current power of attorney or prior written consent. VSOs with access to the VA computer network may only view VACOLS records of individuals for whom they are the representatives of record. VSO access is read only, meaning that they are not able to alter, delete or add to those records. Other properly designated representatives who are not located in buildings that permit access to VACOLS may request a paper copy of the records in this system that pertain to their clients.

Provision for the disposal of digitally recorded material through erasure has been added to the Retention and Disposal section, and will be governed by procedures to be established in Rule 714, 38 CFR 20.714.

Approved: January 11, 2005.

Anthony J. Principi,

Secretary of Veterans Affairs.

44VA01, ''Veterans Appellate Records System-VA,'' as described in the **Federal Register** publication, ''Privacy Act Issuances, 1989 Compilation, Volume II,'' page 904, and amended at 56 FR 15663 (April 17, 1991), 63 FR 37941 (July 14, 1998), and 66 FR 47725 (Sept. 13, 2001) is republished in its entirety below to incorporate the system's merger with 81VA01, ''Representatives'' Fee Agreement

Records System,'' first published at 56 FR 18874 (April 24, 1991) and amended at 57 FR 8792 (March 12, 1992), 63 FR 37941 (July 14, 1998), and 66 FR 47725 (Sept. 13, 2001), and the proposed changes. The system 81VA01, ''Representatives'' Fee Agreement Records System'' is discontinued.

44VA01

SYSTEM NAME:

Veterans Appellate Records System-VA.

SYSTEM LOCATION:

Board of Veterans' Appeals, Department of Veterans Affairs (VA), Vermont Avenue, NW., Washington, DC 20420, at the Wilkes-Barre VA facility, 100 North Wilkes-Barre Boulevard, Wilkes-Barre, PA 18702, and with the Board's contractor, Promisel & Korn, Inc., 3228 Amberley Lane, Fairfax, VA 22031.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Veterans, other appellants, Veterans Law Judges, Board staff attorneys and Members of Congress.

CATEGORIES OF RECORDS IN THE SYSTEM:

The computer database entitled Veterans Appeals Control and Locator System (VACOLS) is a part of this system and includes electronically attached copies of Board of Veterans' Appeals decisions, remands and development memoranda; personal information on appellants and contesting parties including names, addresses, identifying numbers, phone numbers, service dates and issues on appeal; names, addresses and phone numbers of representatives, powers of attorney and attorney fee agreements; information on and dates of procedural steps taken in claims; records of and copies of correspondence concerning appeals, diary entries, notations of mail received, information requests; verbatim recordings and transcripts of hearings; tracking information as to file location and custodian; and employee productivity information. Material in this system that is not maintained in VACOLS includes copies of written fee agreements and documents relating to the filing and review of fee agreements received prior to the Board's practice of electronically attaching fee agreements and powers-of-attorney in VACOLS; microfiche decision locator tables and indices to decisions from 1983 to 1994; and microfiche reels with texts of decisions from 1977 to 1989.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

38 U.S.C. 7101(a), 7104, 5904.

PURPOSE(S):

Initial decisions on claims for Federal veterans' benefits are made at VA field offices throughout the nation. Claimants may appeal those decisions to the Board of Veterans' Appeals. *See* 38 U.S.C. Chapter 71. The Board gathers or creates the records in this system in order to carry out its appellate function, to statistically evaluate the appellate process, to monitor attorney fee agreements, and to evaluate employee performance.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure to law enforcement personnel and security guards in order to alert them to the presence of dangerous persons in VA facilities or at VA activities conducted in non-VA facilities.

2. VA may disclose on its own initiative any information in this system, except the names and home addresses of veterans and their dependents, which is relevant to a suspected or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, to a Federal, State, local, tribal, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule or order. On its own initiative, VA may also disclose the names and addresses of veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto.

3. A record from this system of records may be disclosed to a veteran, claimant or a third party claimant (*e.g.*, a veteran's survivors or dependents) to the extent necessary for the development of that claimant's claim for VA benefits.

4. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

5. Disclosure may be made to the National Archives and Records Administration (NARA) in records management inspections conducted under authority of Title 44 U.S.C.

6. A record from this system (other than the address of the beneficiary) may be disclosed to a former representative of a beneficiary to the extent necessary to develop and adjudicate a claim for payment of attorney fees to such representative from past due benefits under 38 U.S.C. 5904 (d) or to review a fee agreement between such representative and the beneficiary for reasonableness under 38 U.S.C. 5904 (c)(2).

7. Where VA determines that there is good cause to question the legality or ethical propriety of the conduct of a person or organization prospectively, presently or formerly representing a person in a matter before VA, a record from this system may be disclosed, on VA's initiative, to any or all of the following: (1) Applicable civil or criminal law enforcement authorities; (2) a person or entity responsible for the licensing, supervision, or professional discipline of the person or organization prospectively, presently or formerly representing a person in a matter before VA; (3) to other Federal and State agencies and to Federal courts when such information may be relevant to the individual's or organization's provision of representational services before such agency or court. Names and home addresses of veterans and their dependents will be released on VA's initiative under this routine use only to Federal entities.

8. Disclosure may be made to the VA-appointed representative of an employee, including all notices, determinations, decisions, or other written communications issued to the employee in connection with an examination ordered by VA under medical evaluation (formerly fitness-for-duty) examination procedures or Department-filed disability retirement procedures.

9. Disclosure may be made to officials of the Merit Systems Protection Board, or the Office of the Special Counsel, or both, when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions, promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

10. Disclosure may be made to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discrimination practices, examination of Federal affirmative employment programs, compliance with the Uniform Guidelines of Employee Selection Procedures, or other functions vested in the Commission by the President's Reorganization Plan No. 1 of 1978.

11. Disclosure may be made to the Federal Labor Relations Authority,

including its General Counsel, when requested in connection with investigation and resolution of allegations of unfair labor practices, in connection with the resolution of exceptions to arbitrator awards when a question of material fact is raised and matters before the Federal Service Impasses Panel.

12. Disclosure of attorney fee information may be made to the United States Court of Appeals for Veterans Claims when an order of the Board has been applied to that Court in accordance with the provisions of 38 U.S.C. 5904(c)(2).

Note: Any record maintained in this system of records which may include information relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus or sickle cell anemia will be disclosed pursuant to an applicable routine use for the system only when permitted by 38 U.S.C. 7332. To the extent that records contained in the system include information protected by 45 CFR parts 160 and 164, *i.e.*, individually identifiable health information, that information cannot be disclosed under a routine use unless there is also specific regulatory authority in 45 CFR parts 160 and 164 permitting disclosure.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information is kept in a computer database entitled Veterans Appeals Control and Locator System (VACOLS) and backed up on computer tape. Archived records that were created prior to expansion of the BVA's electronic storage capability may be stored in filing folders or cabinets, microfiche, computer disks, computer tape and magnetic tape (hearings). Records in this system are essential to protecting legal and financial rights of individual citizens and the government and are maintained indefinitely as Category B Vital Records. Under the Vital Records Schedule, electronic back-up tapes are updated quarterly. A back-up tape is transferred weekly to the Board's contractor for quick access back-up tape storage. Hearings before the Board are recorded and stored digitally until a transcript has been made. Transcripts are then electronically attached to the record in VACOLS. Attorney fee agreements and related correspondence received prior to the Board's practice of attaching this information in VACOLS are kept in file folders. These files will be scanned into VACOLS, at which time original documents will be forwarded for association with the appropriate claims file. The now discontinued Briefface folders are maintained at the Board according to provisions of General Records Schedule 16, Item 7, for a minimum of 18 months.

RETRIEVABILITY:

VACOLS records in this system may be retrieved by any searchable field in the VACOLS database. This system notice covers only information retrieved by an individual's name or other identifier. Archived material from this system that is not in VACOLS may be retrieved by veteran's name, VA file number, or BVA archive citation number.

SAFEGUARDS:

Files are under custody of designated employees of the Department of Veterans Affairs, including employees of the Board of Veterans' Appeals and its contractor, all of who have a need to know the contents of the system of records in order to perform their duties. Access to VACOLS is strictly limited to reflect the need individual employees have for the different records in the system. Where a VSO office is located in a VA facility and has access to VACOLS through the Wide Area Network (WAN), that access is strictly limited to viewing records of current clients of the organization. No personal identifiers are used in statistical and management reports, and personal identifiers are removed from all archived BVA decisions and other records in this system before VA makes them available to the public. Files kept by the contractor are in a locked safe in locked rooms in a secured building.

RETENTION AND DISPOSAL:

Records in this system, in VACOLS and those collected prior to VACOLS use as a repository, are retained indefinitely as Category B Vital Records unless otherwise specifically noted. Under the Vital Records Schedule, electronic back-up tapes are destroyed by erasure upon receipt of the next quarterly tape set. Transcriptions of recordings of hearings will be attached electronically in VACOLS. Following procedures established in Rule 714, 38 CFR 20.714, transcripts will become the official records of hearings and the recordings will be destroyed through erasure after the hearing subject has had the opportunity to challenge the accuracy of the transcript. Briefface folders are shredded after 18 months as described in General Records Schedule 16, Item 7.

SYSTEM MANAGER(S) AND ADDRESS:

Chairman (01), Board of Veterans' Appeals, 810 Vermont Avenue, NW., Washington, DC 20420.

NOTIFICATION PROCEDURES:

An individual desiring to know whether this system of records contains a record pertaining to him or her, how he or she may gain access to such a record, and how he or she may contest the content of such a record may write to the following address: Privacy Act Officer (01C1), Board of Veterans' Appeals, 810 Vermont Avenue, NW., Washington, DC 20420. The following information, or as much as is available should be furnished in order to identify the record: Name of veteran, name of appellant other than the veteran (if any), and Department of Veterans Affairs file number. For information about hearing transcripts or tape recordings, also furnish the date, or the approximate date, of the hearing.

RECORD ACCESS PROCEDURES:

Individuals seeking information regarding access to information contained in this system of records may write, call or visit the Board of Veterans' Appeals Freedom of Information Act Officer, whose address and telephone number are as follows: Freedom of Information Act Officer (01C1), Board of Veterans' Appeals, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 565–9252.

CONTESTING RECORD PROCEDURES:

(*See* notification procedures above.)

RECORD SOURCE CATEGORIES:

VA Claims, insurance, loan guaranty, vocational rehabilitation, education, hospital records, and outpatient clinic records folders and associated folders; Board of Veterans' Appeals records; data presented by appellants and their representatives at hearings and in briefs and correspondence; and data furnished by Board of Veterans' Appeals employees.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–1991 Filed 2–3–05; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register

Vol. 70, No. 23

Friday, February 4, 2005

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 96

[Docket No. 03–080–3]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities

Correction

In rule document 04–28593 beginning on page 460 in the issue of Tuesday, January 4, 2005, make the following corrections:

1. On page 479, in the second column, in the second paragraph, in the last line, ''CAN'' should read ''CΛN''.

2. On page 481, in the first column, in the first paragraph, in the fifth line, ''CAN'' should read ''CΛN''.

3. On page 498, in third column, in the last paragraph, in the 11th and 12th lines, ''*http://www.cfsan.fda.gov/comm/bsefaq.html*'' should read ''*http://www.cfsan.fda.gov/~comm/bsefaq.html*''.

4. On page 517, in the first column, in the third paragraph, in the ninth line,''$7.3 \times 10_{-3}$'' should read '' 7.3×10^{-3}''.

[FR Doc. C4–28593 Filed 2–3–05; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,

February 4, 2005

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 441, et al.

Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 441, 486 and 498

[CMS–3064–P]

RIN: 0938–AK81

Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish new conditions for coverage for organ procurement organizations (OPOs), including multiple new outcome and process performance measures based on donor potential and other related factors in each service area of qualified OPOs. We are proposing new standards with the goal of improving OPO performance and increasing organ donation.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 5, 2005.

ADDRESSES: In commenting, please refer to file code CMS–3064–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates please):

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3064–P, P.O. Box 8015, Baltimore, MD 21244–8015.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Marcia Newton, (410) 786–5265. Diane Corning, (410) 786–8486.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3064–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Key Statutory Provisions

The Organ Procurement Organization Certification Act of 2000 (section 701 of Pub. L. 106–505) and section 219 of the Conference Report accompanying the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) contain identical provisions that amended section 371(b)(1) of the Public Health Service (PHS) Act (42 U.S.C. 273(b)(1)). The legislation directs the Secretary to establish regulations that include four major requirements. These are to:

1. Increase the re-certification cycle for OPOs from 2 to at least 4 years.

2. Establish outcome and process performance measures based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified OPOs.

3. Establish multiple outcome measures.

4. Establish a process for OPOs to appeal a de-certification on substantive and procedural grounds.

The re-certification cycle was increased from 2 years to 4 years through an interim final rule with comment (December 28, 2001, 66 FR 67109), ''Emergency Re-certification for Coverage for Organ Procurement Organizations (OPOs).'' The interim final rule re-certified all 59 OPOs until December 31, 2005 and extended their agreements with us until July 31, 2006. Thus, the re-certification cycle set forth in the interim final rule satisfies the first of the new criteria (that is, certification not more frequently than once every 4 years.) Our proposed rule addresses the remaining three requirements.

Section 1138 of the Social Security Act (the Act) (42 U.S.C. 1320b–8) provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be reimbursed in hospitals and critical access hospitals under the Medicare or Medicaid programs. Section 1138(b) of the Act also specifies that an OPO must operate under a grant made under section 371(a) of the PHS Act or must be certified or re-certified by the Secretary as meeting the standards to be a qualified OPO. Under these authorities, we previously established conditions for coverage for OPOs at 42 CFR 486.301, et seq. (May 2, 1996, 61 FR 19722).

Section 1102 of the Act gives the Secretary of Health and Human Services the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions with which he is charged under the Act. This section of

the Act gives the Secretary broad authority to establish requirements for OPOs that are necessary for the efficient administration of the Medicare program.

B. Why We Are Proposing New OPO Regulations

OPOs are government contractors that play a crucial role in ensuring that scarce transplantable human organs are provided to seriously ill patients suffering from end-stage organ failure. OPOs are responsible for identifying potential organ donors, informing families about their donation options, obtaining consent to donation, screening potential donors for infectious disease, clinically managing potential organ donors to maintain viability of their organs, placing the maximum number of organs possible with transplant centers, arranging for recovery, testing, and tissue typing of organs, and packaging and transporting organs to transplant hospitals. Clearly, OPO performance is one of the most critical elements of the nation's organ transplantation system. An OPO that is effective in procuring organs and delivering them safely to transplant centers will save more lives than an ineffective OPO. Therefore, under the broad authority in the statute, the Secretary has established performance standards for OPOs so that they excel in their critical mission.

The need for organ donors is acute and growing rapidly. While medical advances have made transplantation a viable treatment option for many patients suffering from end-stage organ failure, the supply of organs has not kept pace with the number of patients who need them. Since 1996 when the current OPO regulations went into effect through the end of 2002, the number of patients waiting for organs increased by nearly 60 percent to more than 80,792, while the number of deceased donors grew by only 14 percent. As of June 23, 2003, there were 82,049 patients waiting for a transplant.

Various studies, including those by the Harvard School of Public Health, the Partnership for Organ Donation, and the Association of Organ Procurement Organizations (AOPO), have estimated that approximately 10,500 to 22,000 deaths occurring in the United States every year could yield suitable donor organs. (C Christiansen, S Gortmaker, J William, et al: A Method for Estimating Solid Organ Donor Potential by Organ Procurement Region, *American Journal of Public Health*, Vol. 88, No. 22, November, 1998. E Sheey, S Conrad, L Brigham, et al: Estimating the Number of Potential Organ Donors in the United States, *The New England Journal of Medicine*, 349:667–74, August 14, 2003. E Guadagnoli, C Christiansen, C Beasley, *Potential Organ-Donor Supply and Efficiency of Organ Procurement Organizations,* Health Care Financing Review, Vol. 24, No. 24, Summer 2003.) However, there were only 6,182 deceased donors in 2002 and only 18,244 transplants resulting from those donations. Based on these estimates, OPOs are recovering organs from, at most, only a little more than half the number of potential donors per year.

The study published in *The New England Journal of Medicine* found that of all potential organ donors reported in the study, only 42 percent became donors. Of those families who were asked to donate, only 39 percent agreed, and 16 percent of families were never asked whether they would agree to donation. The study published in the Health Care Financing Review found that of all potential organ donors reported in the study, only 35 percent became donors.

Over the years, many research studies have analyzed factors that impact donation rates, including health professionals' attitudes toward donation, the setting in which requests for donation are made, and medical examiner prohibitions on donation. Recently, researchers have increasingly turned their attention to the best practices of OPOs whose service areas have high donation rates.

In April 2003, the Health Resources and Services Administration (HRSA) began an ongoing ''Organ Donation Breakthrough Collaborative'' to bring best practices in organ donation to OPOs and hospitals, particularly to hospitals identified as having the greatest number of potential donors. More than three-quarters of the 59 OPOs are participating in the Collaborative. By studying the practices of six of the best-performing OPOs, the Collaborative's researchers have already identified several best practices for OPOs, as well as strategies for implementing them. Many of the best practices and associated strategies are discussed throughout this preamble to provide guidance for OPOs in implementing the requirements of the proposed rule.

Our proposals would fundamentally change the existing OPO regulations to emphasize quality and continuous quality improvement. The changes would ensure that each OPO utilizes best practices to improve its efficiency, effectiveness, and quality. While the requirements in the proposed rule apply to all OPOs, we have specifically targeted the requirements toward OPOs that may not understand the value of incorporating best practices into the structure of their organizations. Thus, our overall goal is to improve the functioning of poor performing OPOs, rather than simply to terminate them.

In April 2001, the Department of Health and Human Services (the Department) launched ''The Secretary's Donation Initiative,'' a multi-pronged effort to increase all types of donation—blood, marrow, tissue, and organ. In his speech launching the Initiative, the Secretary noted, ''The facts are just astounding. Someone dies every 96 minutes because there aren't enough organs to go around.'' The five initial key elements of the Initiative were the Workplace Partnership for Life, a new model donor card, a national forum on donor registries, a national gift of life medal, and a drivers' education donation curriculum. The Department promised that it would launch additional elements under the Initiative in the future. The Organ Donation Breakthrough Collaborative is the sixth key element of the Secretary's Initiative. The Secretary believes promulgation of the multiple outcome and process performance measures in this rule will improve OPO performance and, as a result, increase organ donation and transplantation in the United States.

B. Overview of Key Proposed Provisions

1. Appeals and Competition Processes

In the congressional findings associated with section 219 of the Conference Report accompanying the Consolidated Appropriations Act, 2001 (42 U.S.C. 219(a)(2)) Congress found that the process for OPO re-certification created a level of uncertainty among OPOs that interfered with their effectiveness in increasing organ donation. Therefore, Congress directed the Secretary to develop a process for OPOs to appeal a de-certification on substantive and procedural grounds. (See section 219(c)(3) codified at 42 U.S.C. 273(b)(1)(D)(ii)(iv).) Under this authority, we are proposing a streamlined appeals process, in which an OPO facing de-certification could appeal and receive a decision on its appeal before its service area is opened for competition from other OPOs. (See proposed § 486.314.)

To further reduce the level of uncertainty identified by Congress, we propose making certain changes in the current re-certification process. Although we would open every OPO's service area for competition at the end of every re-certification cycle as under the current regulations, we would: (1) Permit OPOs to compete for open areas only if they met certain specific objective criteria; (2) allow competition only for entire service areas; and (3) use

clear, objective criteria for determining which OPO would be designated for the service area (See proposed § 486.316.)

A more extensive discussion of our proposal for the appeals and competition processes, as well as a description of other competition processes on which we are requesting comments, can be found in this preamble under proposed ''General Requirements.''

2. Proposed Multiple Outcome Performance Measures

When we published the current OPO regulations in 1996, population was the only measure readily available to assess donor potential. Therefore, we promulgated regulations that judge an OPO's performance based on the population in its service area (for example, the number of donors per million population). Subsequently, we began to investigate alternative methods for assessing donor potential in order to develop new outcome measures based on the organ donation potential in each OPO's service area. This preamble contains a discussion of our analysis of these alternative methods, as well as an explanation of the method we propose—using potential donor data reported by OPOs to the Organ Procurement and Transplantation Network (OPTN) based on information from hospital referral calls to OPOs. A discussion of the proposed multiple outcome measures can be found in this preamble under ''OPO Outcome Performance Measures.'' The proposed regulatory text can be found at § 486.318.

The proposed outcome measures would address two requirements of the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001. The first requirement calls for promulgation of ''outcome* * *performance measures that are based on empirical evidence obtained through reasonable efforts of organ donor potential and other related factors in each service area of qualified organ procurement organizations.'' The second requirement calls for the use of ''multiple outcome measures as part of the certification process.''

3. Proposed Multiple Process Performance Measures

In addition to proposing multiple outcome measures, the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001 require the Secretary to propose ''process performance measures that are based on empirical evidence obtained through reasonable efforts of organ donor potential and other related factors in each service area of qualified organ procurement organizations.'' In the congressional findings associated with section 219 of the Conference Report accompanying the Consolidated Appropriations Act, 2001 (Pub. L. 106–554, 42 U.S.C. 219(a)(6)(B)), Congress urged us to ''improve the overall certification process'' by incorporating process as well as outcome performance measures. Congress noted that current OPO regulations do not permit consideration of outcome and process performance measures that ''would more accurately reflect the relative capability and performance of each organ procurement organization.''

Therefore, we propose to establish outcome and process performance-related measures based on factors that affect an OPO's ability to provide the maximum number of healthy organs to transplant centers. The purpose of these measures is to improve OPO performance and increase organ donation by ensuring that OPOs attain the highest possible level of effectiveness and quality. The process performance measures we propose would require OPOs to develop performance protocols, monitor their own performance continuously, and make changes to improve the quality of their organizations.

The proposed new process performance measures are based on empirical evidence of organ donor potential and other related factors in each OPO service area derived from three bodies of knowledge: (1) Research into best practices in organ donation, (2) information about methods of maximizing organ donation based on our work with OPOs, and (3) accepted standards of practice and quality improvement strategies used by the larger health care community.

A review of the literature on best practices in organ donation provides empirical evidence that certain characteristics are common to successful OPOs. These characteristics include experienced leadership; efficient mechanisms for tracking activity; excellent communication with transplant hospitals; timely, on-site response to donor referrals; adequate experienced staff; data-driven decision making; in-hospital coordinators; and targeted hospital development programs. We have incorporated findings from the literature into the proposed process performance measures. Discussions and citations of individual studies can be found in this preamble in ''Organ Procurement Organization Process Performance Measures.''

Our experience with top-performing OPOs supports the validity of the literature on best practices. In 1998, we developed four ''OPO Coordinator'' positions in the four CMS Regional Consortia (Midwest, West, South, and Northeast). The OPO Coordinator positions are unique; OPOs are the only Medicare providers or suppliers that have our staff assigned to work with them on an ongoing basis to improve their quality and outcomes. The Coordinators sponsor seminars, conduct conferences and workshops, provide education for OPO staffs, conduct site visits, meet with OPO directors and hospital development staffs, recommend interventions to increase OPO efficiency and quality, analyze OPO's voluntary quality improvement efforts, and act as liaisons between OPOs and hospitals and between OPOs and tissue banks to resolve problems and promote cooperation. (We would note that for ease of use, the term ''tissue bank'' when used in this preamble and in the proposed regulations text refers to all types of tissue banks, including those that recover only corneas and eyes, and the word ''tissues'' refers to all types of tissues, including corneas and eyes.)

The proposed process performance measures are based heavily on the Coordinators' extensive experience with all 59 OPOs. The Coordinators' experience with and knowledge about OPOs provide much of the empirical evidence that has enabled us to develop proposed process performance measures targeted specifically toward increasing OPO performance and quality.

As stated earlier, some of the proposed requirements are based on other factors such as accepted standards of practice for all health care organizations. For example, proposed § 486.344 would require OPOs to use accepted standards of practice for testing donors to prevent transmission of the human immunodeficiency virus (HIV) and other infectious diseases. Proposed § 486.348 is based on quality assessment and performance improvement (QAPI) programs that have been embraced by the health care community and that have been shown to increase quality and outcomes of care.

Therefore, the process performance measures we propose would satisfy the second requirement in the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001 for the Secretary to propose process performance measures ''based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in

each OPO's service area.'' These include the following proposed requirements for OPOs:

- Have agreements with hospitals and critical access hospitals that address responsibilities in regard to the requirements for hospitals at § 482.45 and for critical access hospitals at § 485.643. (§ 486.322.)
- Maintain sufficient qualified staff (either from the OPO or under contract or arrangement) to accomplish a number of different objectives, including screening referral calls for donor potential, assessment of potential donors for medical suitability, requesting consent, maintaining donors, placing organs, overseeing organ recovery, performing death record reviews, and conducting QAPI activities. (§ 486.326.)
- Ensure that organ recovery personnel are qualified and trained. (§ 486.326.)
- Provide education, training, and performance evaluations for OPO staff. (§ 486.326.)
- Obtain informed consent for organ and tissue donation. (§ 486.342.)
- Develop and follow protocols for donor evaluation and management and organ placement and recovery. (§ 486.344.)
- Have a medical director who is responsible for implementation of these protocols, as well as oversight management of potential donors. (§ 486.326.)
- Arrange for screening and testing of the donor for infectious disease and testing and tissue typing of organs by a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1998. (§ 486.344 and § 486.346.)
- Collaborate with transplant programs and have protocols defining OPO and transplant hospital roles and responsibilities for donor evaluation, donor management, organ recovery, and organ placement. (§ 486.344.)
- Document recipient information, including blood type and position on the wait list, before organ recovery. (§ 486.344.)
- Develop and follow a protocol for packaging, labeling, handling, and shipping organs. (§ 486.346.)
- Establish a comprehensive, data-driven, QAPI program designed to monitor and evaluate performance of all donation services. (§ 486.348.)
- Perform death record reviews in hospitals with level I or level II trauma centers or 150 or more beds. (§ 486.348.)

In addition, we propose a number of other requirements based on the Secretary's authority under section 1102 of the Act to establish requirements necessary for the efficient administration of the Medicare program. These requirements generally are related to (1) administrative matters (because efficient administration by Medicare contractors such as OPOs supports efficient administration of the Medicare program); (2) OPOs' relationships with Medicare donor and transplant hospitals; and (3) data collection, management, and reporting (because OPO data are needed by other Medicare entities, by other agencies within the Department, and by us for the certification of OPOs.) These proposed requirements include:

- Participation in the Organ Procurement and Transplantation Network. (§ 486.320.)
- Designated requestor training for hospital staffs. (§ 486.322.)
- Legal authority of a governing body for management and provision of OPO services and development and implementation of policies and procedures for administration of the OPO, the OPO's QAPI program, and services furnished under contract or arrangement. (§ 486.324.)
- Conflict of interest policies for the governing body, OPO directors, medical directors, senior management, and procurement coordinators. (§ 486.324 and § 486.326.)
- Credentialing records for organ recovery personnel. (§ 486.326.)
- Hospital-specific organ donation and transplantation data reported to Secretary and public. (§ 486.328.)
- Information management, including donor and transplant recipient information, data retention, and format of records. (§ 486.330.)
- A system to allocate donated organs that is consistent with the rules and requirements of the OPTN. (§ 486.344.)
- Investigation, analysis, and reporting of adverse events to us. (§ 486.348.)

Some of the proposed process performance measurements have a dual role in that they both satisfy the requirements of the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001 and are based on the Secretary's authority under section 1102 of the Act. For example, the requirement for OPOs to provide designated requestor training for hospitals can be linked to the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001 because the requirement is based on empirical evidence that shows improved consent rates when the OPO and hospital collaborate in requesting consent. (Note that factors in each OPO's service area, such as the OPO's relationship with its hospitals, would determine whether hospitals would request, and OPOs would need to provide, designated requestor training). This proposed requirement also is necessary to the effective and efficient administration of the Medicare and Medicaid programs because under 42 CFR § 482.45, hospitals must ensure that individuals who discuss donation with families of potential organ donors are trained in a course offered or approved by the OPO.

Finally, section 1138(b)(1)(A) of the Act requires an OPO to be a ''qualified'' OPO as described in section 371(b) of the PHS Act. A number of the requirements we propose (for example, arrangements to cooperate with tissue banks and membership composition and authority of OPO boards) are based on requirements for qualified OPOs under the PHS Act. (See § 486.322 and § 486.324.) Proposed requirements that relate to the PHS Act are noted in the broader discussion in this preamble under ''Proposed Process Performance Measures and Other Requirements.''

II. Provisions of the Proposed Regulations

For the reasons discussed above, we propose to reorganize and revise 42 CFR part 486, subpart G. Following is a discussion of the specific requirements contained in the proposed conditions.

Proposed General Requirements

Basis and Scope (Proposed § 486.301)

Section 486.301 (Basis and scope) would remain unchanged from the existing regulations except that we would add a reference to § 1102 of the Act, and we would add the term, ''non-renewal'' to § 486.301(b)(3) to clarify that the scope includes non-renewal of agreements.

Definitions (Proposed § 486.302)

To reflect organizational changes in the regulations text, to remove obsolete material, and to provide further clarity to the regulations, we propose several amendments and additions to the definitions.

We propose amending the definition for ''certification'' to mean a Secretarial determination that an OPO meets (or has met) the requirements at 42 CFR 486.303 and is eligible for designation if it meets the additional requirements for designation.

We propose amending the definition of ''designation'' to clarify that designation is the process of assigning geographic service areas to OPOs. Once an OPO is certified and assigned a

geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under § 1138(b)(1)(F) of the Act.

We propose amending the definition of ''entire metropolitan statistical area'' to state that we do not recognize consolidated metropolitan statistical areas (CMSAs) when making service area determinations.

We propose amending the definition of ''organ'' to clarify that the definition includes multivisceral organs only when they are transplanted with an intestine.

We propose eliminating ''potential donor'' and replacing it with ''organ donor potential.'' The definition of ''potential donor'' in the current regulations refers to causes and conditions of death that are ''generally acceptable'' for donation of at least one solid organ.'' In our definition for ''organ donor potential,'' we would include specific parameters for the cause and conditions of death that indicate medical suitability for organ donation. These parameters are discussed in this preamble under ''Proposed OPO Outcome Measures,'' section C3. We are particularly interested in public comments on this proposed definition.

We propose replacing ''transplant center'' with ''transplant hospital'' and have standardized the use of ''transplant hospital'' throughout this proposed regulation. A transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ transplant centers operating within the same transplant hospital.

Additionally, we propose adding definitions for ''adverse event,'' ''agreement cycle,'' ''death record review,'' ''de-certification,'' ''designated requestor,'' ''donor,'' ''donor document,'' ''potential donor denominator,'' and ''re-certification cycle.''

We propose a definition for ''adverse event'' because we propose requiring an OPO to report those events to us so that we can monitor the OPO's response to the adverse event. An adverse event would mean an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.

We propose definitions for ''agreement cycle'' and ''re-certification cycle'' to clarify the difference between the two. The 4-year CMS/OPO agreement cycle runs from August 1 through July 31, unless it is extended according to § 486.314. The 4-year re-certification cycle is based on the calendar year.

We have included a proposed definition for ''death record review'' because we would require OPOs to perform death record reviews as part of their QAPI programs.

We have included a definition for ''de-certification'' to explain that de-certification follows our determination that an OPO no longer meets one or more conditions for coverage (including, the outcome measures at § 486.318 and the process performance measures and other requirements) or no longer meets the requirements for certification or designation. If an OPO's agreement with us is terminated or is not renewed, the OPO is de-certified.

We propose adding a definition for ''designated requestor'' to explain the role of designated requestors in the donation process. We propose a definition for ''donor'' to ensure that OPOs'' reporting of donor data is standardized. (The definition of ''donor'' is not intended to limit acceptable donors.)

We are proposing a definition for ''donor document'' because we would require OPOs to ensure that, in the absence of a donor document, the individual or individuals with responsibility to make the donation decision are informed of their option to donate organs or tissues or to decline to donate.

We propose adding ''potential donor denominator'' to the definitions because we would use this term for the potential donor data OPOs would report to the OPTN. Those data would be used as the basis for the multiple outcome measures.

These definitions, as we propose to add or revise them, are contained in the regulatory text section at the end of this document.

Requirements for Certification and Designation

[If you choose to comment on this section, please include the caption ''Certification and Designation Requirements'' at the beginning of your comments.]

Requirements for Certification (Proposed § 486.303)

The current regulations do not make a clear distinction between the requirements necessary for certification and the requirements necessary for designation, nor do they specify that an OPO must be certified before it is designated for a service area. Therefore, we propose adding a new section to specify the requirements an OPO must meet to be certified.

Following are the proposed requirements. After each proposed requirement, we have listed the location of the requirement in the statute or in current regulations. To be certified, an OPO must:

(1) Have received a grant under 42 U.S.C. 273(a).

(2) Be a non-profit entity that is exempt from Federal income taxation under § 501 of the Internal Revenue Code of 1986. (See § 486.306(a).)

(3) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals. (See § 486.306(b).)

(4) Have an agreement with the Secretary to be reimbursed under title XVIII for the procurement of kidneys. (See section 371(b)(1)(C) of the PHS Act.)

(5) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005. (See § 486.301(b)(4).)

(6) Have procedures to obtain payment for non-renal organs provided to transplant centers. (See § 273(b)(1)(E).)

(7) Agree to enter into an agreement with any hospital in the OPO's service area, including a transplant hospital, that requests an agreement. (See 486.304(b)(8).)

(8) Meet or have met the conditions for coverage, including the outcome measures and the process performance measures and other requirements. (See § 486.314. This section states that an OPO's agreement with CMS may be terminated if the OPO does not meet the two conditions for coverage in the current regulations, as well as the requirements for qualifications for designation found in § 486.306.)

We propose that these threshold requirements for certification must be met before an OPO can be designated, pursuant to our proposed § 486.304.

Requirements for Designation (Proposed § 486.304)

Provisions regarding general requirements for designation as an OPO currently found in § 486.304 (''General requirements'') and requirements at § 486.306 (''Qualifications for designation as an OPO'') would be reorganized. Some requirements found in current § 486.304 have been moved to proposed § 486.303. Other requirements judged to be burdensome or unnecessary have been removed. For example, we would no longer require

OPOs to submit a written application for designation.

Most requirements in the current § 486.306 would be incorporated into other sections of the proposed rule. Specifically, requirements for OPO advisory boards and boards of directors have been moved to proposed § 486.324 (''Administration and governing body''). Requirements for agreements with hospitals, critical access hospitals, and tissue banks can be found in proposed § 486.322 (Relationships with hospitals, critical access hospitals, and tissue banks). Requirements for testing of donors and organs can be found in both proposed § 486.344 (Donor evaluation and management and organ placement and recovery) and proposed § 486.346 (Organ preparation and transport). Requirements for data reporting have been moved to proposed § 486.328 (Reporting of data), and requirements for protecting privacy of data can be found in proposed § 486.330 (Information management). Finally, requirements for professional education can be found in § 486.326 (Human resources). Our rationale for these proposed changes is addressed later in this preamble in our discussion of the individual sections.

In addition, we propose requiring OPOs to file a cost report within 5 months following the end of the fiscal year, rather than the current 3 months. This would conform the OPO regulations to § 413.24(f).

OPO Service Area Size Designation and Documentation Requirements (Proposed § 486.306)

The requirements contained in this section would be re-designated from the current § 486.307, and many requirements would remain unchanged. We would no longer require OPOs to provide population data to us since population would no longer be used as a basis for OPO certification.

We propose retaining the requirement that an OPO must procure organs from an average of at least 24 donors per calendar year. We believe it is important to retain this requirement to assure that each OPO has ''a defined service area of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs* * *'' as Congress intended. (See section 371(b)(1)(F) of the PHS Act.) In addition, we would change the current requirement for an average of 24 donors per calendar year in the 2 years before the year of re-designation to a requirement for an average of 24 donors per calendar year in the 4 years before the year of re-designation because the re-certification cycle has been increased from 2 years to 4 years.

However, we would no longer permit exceptions to the 24-donor per year rule, including the exception for an OPO that serves an entire state. (See § 486.307(d)(2)(ii).) When the current regulations were published in 1996, the average OPO recovered 77 donors per year. Because of a decrease in the number of OPOs and an increase in the number of donors recovered nationwide, the average OPO procured approximately 100 donors in 2002. Therefore, we believe that an OPO procuring fewer than 96 donors in a 4-year period is too small to operate efficiently and effectively.

We propose removing language from the current regulations that refers to new entities or organizations becoming OPOs. Section 371(a) of the PHS Act provides authority for the Secretary to make grants to qualified OPOs that are described in subsection (b). However, given the provision in (b)(1)(D) added by the OPO Certification Act of 2000 (''notwithstanding any other provision of law, has met the requirements of this section and has been certified or re-certified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization* * *''), it appears impossible for the Secretary to give a grant to an organization that was not one of the 59 OPOs that was certified by the Secretary as meeting the performance standards in the 4-year period before January 1, 2000.

Therefore, we propose removing the language at § 486.307(d)(2)(iv) that requires an entity to show that it can procure organs from at least 50 potential donors per year if it was not previously designated as an OPO. We also propose removing references related to designation of or requirements for entities or organizations that are not currently OPOs

Additionally, we would remove obsolete service area size standards for periods during 1996 and before. We would change the current requirement for submission of information about acute care hospitals that have an operating room and the equipment and personnel to retrieve organs to submission of information about hospitals that have both a ventilator and an operating room, since we propose requiring OPOs to have agreements with 95 percent of those hospitals. (See discussion in this preamble of § 486.322, Relationships with hospitals, critical access hospitals, and tissue banks). Finally, we would increase the designation period from 2 years to 4 years to conform the designation period to the re-certification cycle.

Designation of One OPO for Each Service Area (Proposed § 486.308)

Requirements for the designation of one OPO for each service area would be moved from § 486.316 to proposed § 486.308. Many requirements would remain unchanged. However, we propose replacing the ''tie-breaker criteria'' used to designate an OPO when two or more OPOs apply for the same area with new criteria found in proposed § 486.316 (''Re-certification and competition processes''). (See discussion of proposed § 486.316 in this preamble for a discussion of the proposed criteria.)

Changes in Ownership or Service Area (Proposed § 486.310)

The requirements for an OPO changing ownership or changing its service area found in § 486.318 would be moved to proposed § 486.310. Many requirements would remain unchanged. However, we propose requiring certain additional information if there is a change in ownership of an OPO. The OPO would be required to provide information specific to the board structure of the new organization to ensure that all required representatives are included. In addition, the OPO would be required to submit operating budgets, financial information, and other written documentation we determine to be necessary for designation to ensure that the OPO continues to meet the requirements for designation.

De-Certification (Proposed § 486.312)

[If you choose to comment on this section, please include the caption ''De-certification'' at the beginning of your comments.]

Many of the requirements contained in § 486.325 (''Termination of agreement with CMS'') would be moved to proposed § 486.312, but the title of the section would be changed to ''De-certification,'' to reflect the fact that if an OPO's agreement with us ends (whether through voluntary or involuntary termination or non-renewal of the OPO's agreement), we would de-certify the OPO.

The paragraph titled ''Voluntary termination'' would remain substantially unchanged, but the paragraph would be renamed ''De-certification due to voluntary termination of agreement.'' Additionally, we would add language to indicate that we would de-certify the OPO as of the effective date of the voluntary termination. The paragraph

titled ''Involuntary termination'' also would remain substantially unchanged, but the paragraph would be renamed ''De-certification due to involuntary termination of agreement.'' Additionally, we propose adding language to indicate that we would de-certify the OPO as of the effective date of the involuntary termination.

We propose adding a paragraph titled, ''De-certification due to non-renewal of agreement,'' which states that we will not renew an OPO's agreement if the OPO fails to meet the outcome measures at § 486.318 based on data from the most recent re-certification cycle or if the OPO is no longer designated for the service area. In that case, we would de-certify the OPO as of the ending date of the agreement. We propose removing the paragraph titled, ''Appeal right,'' because we propose a new appeals process in § 486.314.

In proposed § 486.312(d), we have retained our general policy of providing an OPO with at least 90 days notice before a de-certification would be effective. However, we propose that in cases of urgent need, notice of de-certification would be given at least three days before de-certification. We expect that cases where an OPO would need to be replaced based on urgent need would be extremely rare. Nevertheless, in unusual circumstances, this expedited time frame may be necessary to protect the public health. The notice to the OPO would specifically state the reason for de-certification and the effective date. We propose changing the title of the paragraph, ''Effects of termination'' to ''Effects of de-certification.'' We propose retaining the paragraph, ''Public Notice,'' but we would add language that states we would give public notice of involuntary termination or non-renewal of agreement in local newspapers in the OPO's service area.

Finally, we propose eliminating the paragraph, ''Reinstatement'' because our proposed appeals process sets forth the process we would use for an OPO whose de-certification was reversed by a CMS hearing officer. If a hearing officer upheld a de-certification, we would not voluntarily reinstate the de-certified OPO. Thus the current language regarding reinstatement would no longer be needed.

Appeals (Proposed § 486.314)

[If you choose to comment on this section, please include the caption ''Appeals'' at the beginning of your comments.]

Under existing regulations, an agreement with an OPO could be involuntarily terminated for failure to meet the conditions for coverage, and any resulting appeals were governed by regulations at 42 CFR part 498. If an OPO failed the outcome performance standards set forth in 486.310, we de-certified the OPO as of August 1 of the year following the end of the re-certification cycle. Although the OPO was given the right to appeal under part 498, it was not possible to complete the appeals process prior to expiration of our agreement with the OPO on August 1. Therefore, we opened the OPO's service area to competition from other OPOs as soon as the OPO was notified about the de-certification. The existing time frame generally did not permit a decision to be made on an appeal prior to a successor OPO taking over the service area when the de-certified OPO's agreement with us expired on August 1. In order to resolve this problem, we propose to make changes to the appeals process and alter the timing of the competition. Specifically, we would: (1) Delay competition until an appeal is completed; (2) expedite appeals by using a CMS hearing officer; and (3) extend an OPO's agreement beyond August 1 if necessary.

In the OPO Certification Act of 2000, Congress specified that we must propose a process whereby an OPO could appeal a de-certification on substantive or procedural grounds. (See section 273(b)(D)(ii)(IV).) Therefore, we are proposing a process whereby an OPO facing de-certification due to involuntary termination or non-renewal of its agreement with us would be able to appeal the de-certification on substantive or procedural grounds and receive a decision on its appeal before its service area was opened for competition from other OPOs. We believe the proposed appeals process would be both fair and expeditious.

An OPO would have 30 calendar days from the date on the notice of de-certification to submit an appeal to a CMS hearing officer. In the appeal, the OPO would be given the opportunity to submit evidence to show why it should not be decertified. Appeals could be based on substantive and/or procedural grounds. Within 2 weeks of receipt of the OPO's appeal, the CMS hearing officer would schedule a hearing. The hearing officer would issue notice of his or her decision to the OPO by certified mail within 2 weeks following the date of the hearing.

In making an appeal on substantive grounds, an OPO could submit evidence of factors that negatively impacted organ donation in its service area and prevented it from meeting the outcome or process performance measures or other requirements. For example, an OPO might have evidence that its ability to obtain consent from families of potential donors was adversely affected by certain demographic factors in its service area, such as the presence of a significant number of citizens whose race, ethnicity, religion, or educational level may be associated with lower rates of consent to organ donation. As another example, an OPO might have evidence that its ability to recover and transport organs to transplant centers while they are still viable for transplantation was hampered by the remote location of many of its donor hospitals.

Since most OPOs have some factors in their service areas that work against organ donation, the failing OPO would need to demonstrate not only the specific factors that affected its ability to meet the outcome measures but also what it did to attempt to ameliorate the factors. For example, if an OPO provided data to show that it has a high minority population that historically has had a lower rate of consent to donation, the OPO would have to demonstrate what it did to address the situation (such as conducting targeted public education) and whether these efforts were successful.

Evidence submitted by an OPO about substantive factors could include, but would not be limited to, research studies, demographic studies, data from the OPO's QAPI program, and information on the OPO's public and professional education and hospital development activities.

In making an appeal on procedural grounds, an OPO could, for example, provide evidence that incorrect data were used by us to determine whether the OPO met the outcome measures.

We propose that if the hearing officer reversed our determination to de-certify an OPO in a case involving the involuntary termination of the OPO's agreement, we would not de-certify the OPO. An OPO that was successful in its appeal would have a right to compete for this service area for the next cycle.

If the de-certification determination was upheld by the hearing officer, Medicare and Medicaid payment would not be made for organ procurement services the OPO furnished on or after the effective date of de-certification. The unsuccessful OPO would not be permitted to compete for the service area, or any other service area.

As stated earlier, OPOs currently have the right to appeal a de-certification under part 498, which sets forth procedures for providers and suppliers to appeal decisions that affect participation in the Medicare program. Since this proposed rule includes an appeals process for OPOs that is

separate from the part 498 process, we propose that if a hearings officer denied an OPO's appeal, the OPO would have no further administrative appeal rights. Thus, we propose removing OPOs from the definition of suppliers found at § 498.2.

However, we note that section 901 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) defines the term ''supplier'' to mean ''unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title [title XVIII].'' Nevertheless, the unique nature of OPOs and their special role in the Medicare program distinguishes them from other suppliers. Typically, suppliers furnish medical items and services directly to Medicare beneficiaries and obtain direct payment for Medicare-covered items and services from a Medicare carrier. A supplier may furnish one or more of the health care items included within the definition of ''medical and other health services'' that are defined in section 1861(s) of the Act and are included in the scope of the part B program. (See section 1832 of the Act.) Many suppliers do not have a formal participation agreement with the Secretary. (See section 1842(h) of the Act.) In contrast, an OPO is required to have an agreement with the Secretary. (See 42 U.S.C 273(b)(1)(C).) Moreover, many, if not most, organ donors are not Medicare beneficiaries, and many organs recovered by OPOs are not transplanted into Medicare beneficiaries.

Given this framework, and to ensure that Medicare pays appropriately for its share of organ acquisition costs, OPOs have payment rules and methodologies that differ from the payment rules and methodologies used for other suppliers. (See, for example, 42 CFR § 413.200.) Among other differences, organ acquisition costs are not paid directly by a carrier to an OPO. Instead, the OPO is paid by the transplant hospital, subject to later adjustment (see 42 CFR 413.200(c)(iv)), and Medicare pays the transplant hospital for the organ acquisition costs. If necessary, Medicare payment to the OPO is adjusted after it files its yearly cost report; for example, if the OPO's costs to recover organs exceeded the payments it received for the organs, Medicare covers the additional costs, based on the percentage of organs that were recovered and transplanted into Medicare beneficiaries. However, for purposes of the adjustment, all organs provided by the OPO to Medicare-approved transplant centers are considered to be organs that were transplanted into Medicare beneficiaries. Since approximately 64 percent to 74 percent of extra-renal organ transplant centers and approximately 100 percent of kidney transplant centers are Medicare approved, the Medicare program reimburses OPOs for their excess costs for most of the organs they recover. Thus, the legal relationship between an OPO and the Medicare program is different from other ''suppliers'' and reflects important statutory differences.

The MMA also requires the Secretary to establish in regulations a provider and supplier enrollment process that includes an appeals process. Section 936 of MMA states that suppliers ''whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection [1866](h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary. Although the appeals process we propose for OPOs differs from the MMA appeals process, it specifically addresses the congressional findings associated with the OPO Certification Act of 2000 that the uncertainty of the current re-certification interferes with the effectiveness of OPOs in raising the level of donation. This alternative appeals process is necessary because there is a limited time period from the date that the outcome performance measure data are available to the date when the OPO contract cycle ends. Therefore, to achieve the goals of the 2000 legislation, including providing an equitable process for appeals, OPO appeals must be expedited and completed before a replacement OPO is named in order to avoid disruption in organ procurement.

Under our proposed rule, if the hearing officer upheld a de-certification determination, we would open the OPO's service area for competition from other OPOs. The de-certified OPO would not be permitted to compete for the open area, and in most cases, the de-certification would be effective as of the ending date of the OPO's agreement with us.

However, if the appeals process did not leave sufficient time for us to conduct a competition process for the open area and provide for a smooth transition of the service area to the successor OPO, we could, at our discretion, extend the OPO's agreement with us for a period of time not to exceed an additional 60 days.

We believe the appeals process we propose fully satisfies the statutory requirement to provide a process for an OPO to appeal a de-certification on substantive and procedural grounds. Although the process is streamlined to allow an OPO to receive a decision on its appeal before the effective date of the de-certification and before its service area being opened for competition, it allows ample time for the OPO to prepare and present evidence of the substantive or procedural basis for its appeal. Furthermore, the process allows sufficient time for a hearing officer to consider the evidence and make a fair decision that affords all of the process that is due to the OPO, while safeguarding our ability to remove and replace an OPO that has not performed well.

Re-Certification and Competition Processes (Proposed § 486.316)

[If you choose to comment on this section, please include the caption ''Re-certification and competition'' at the beginning of your comments.]

Congress stated in the congressional findings associated with section 219 of the Consolidated Appropriations Act, 2001 that the OPO re-certification process ''created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of donation.'' Under existing regulations at § 486.310 and § 486.316, the service area of every OPO was opened for competition at the conclusion of every re-certification cycle, regardless of whether the OPO met the outcome performance standards for the prior re-certification cycle. Any OPO that met the performance standards for the prior re-certification cycle was eligible to compete for an open service area or a portion of an open service area.

Under existing OPO regulations, an OPO that failed to meet the outcome measures would lose its service area and be de-certified. Its service area would be opened for competition from all OPOs that met the outcome performance standards. If no OPO that met the outcome performance standards was willing to accept responsibility for the service area, the OPO that failed the outcome performance measures would be re-designated for the service area if it submitted an acceptable corrective action plan to us.

Under existing regulations, if more than one OPO that met the performance standards wanted to take over the service area or part of the service area of another OPO, we used six ''tiebreaker'' criteria to determine which OPO should be awarded the service area. The tiebreakers were: (1) Prior performance, including the previous

year's experience in terms of the number of organs retrieved and wasted and the average cost per organ; (2) actual number of donors compared to the number of potential donors; (3) the nature of relationships and degree of involvement with hospitals in the organization's service area; (4) bed capacity associated with the hospitals with which the organizations have a working relationship; (5) willingness and ability to place organs within the service area; and (6) proximity of the organization to the donor hospitals.

As stated earlier in this preamble, we propose opening every OPO's service area for competition at the end of every re-certification cycle as we did under the existing regulations. However, we are proposing certain limitations that we believe would address the uncertainty in the re-certification process that was noted by Congress. The limitations would ensure that: (1) The process can be completed expeditiously; (2) disruptions to service areas will be minimized; and (3) an OPO may compete for an open area only if it is likely to be able to improve organ donation in the service area.

The proposed competition process would differ somewhat, depending upon whether a service area was opened for competition because the incumbent OPO was de-certified or because of the wider competition process taking place at the end of a re-certification cycle. First, we would permit OPOs to compete for open areas only if they met certain specific objective criteria. These criteria would vary, depending upon whether the incumbent OPO was or was not de-certified. Second, we would allow competition only for entire service areas. A service area could be divided only if the incumbent OPO was de-certified and no OPO wanted to accept responsibility for the service area. In such case, we could, at our discretion, choose a single OPO to take over the service area or adjust the service area boundaries of two contiguous OPOs to incorporate the open area. Finally, we are proposing to use specific clear, objective criteria for determining which OPO would be selected for a service area.

The chart below shows how the process would differ. Following the chart is a more detailed explanation of our proposal.

Incumbent OPO decertified?	Incumbent OPO permitted to compete?	Can service area be divided?	Criteria OPOs must meet to compete for open area	Criteria CMS uses to choose OPO
Yes	No	Yes, at discretion of CMS.	4 out of 5 outcome performance measures at or above the mean.	Acceptable plan to increase organ donation in open area.
No	Yes	No	4 out of 5 outcome performance measures at or above the mean. Conversion rate (actual donors as a percentage of potential donors) at least 15 percentage points higher than incumbent's conversion rate.	Acceptable plan to increase organ donation in open area.

Competition When OPO Has Been De-Certified

We propose that if we notify an OPO that it will be de-certified because its agreement will be terminated or will not be renewed and the OPO does not appeal within the time frame specified in § 486.314(a) or the OPO appeals but the de-certification is upheld (see § 486.314(c)), we would open the OPO's service area for competition from other OPOs. An OPO's service area would not be opened for competition until the conclusion of the proposed appeals process.

Only OPOs that meet 4 out of 5 outcome performance measures at or above the mean for the preceding re-certification cycle would be eligible to compete for the open service area of a de-certified OPO. The de-certified OPO would not be permitted to compete for its service area, or any other service area. Competing OPOs would be permitted to compete only for the entire service area.

By requiring an OPO to have attained the mean or greater in 4 out of the 5 outcome performance measures in order to compete for the open area of a de-certified OPO, we would limit competition to OPOs that have performed significantly better than the failing OPO. That is, the overall performance of an OPO that meets 4 out of 5 outcome performance measures at or above the mean would be, at the least, approximately 25 percentage points higher overall than the performance of an OPO that is de-certified because it did not meet 4 out of 5 outcome performance measures at 75 percent of the mean. We propose establishing the threshold at 100 percent of the mean for 4 out of 5 outcome performance measures because we believe that an OPO whose performance is at or above the mean would have the expertise needed to take over a failing OPO's service area and improve organ donation.

OPOs would be permitted to compete only for entire service areas. We have found that permitting competition for partial service areas provides an incentive for OPOs to attempt to ''raid'' portions of neighboring service areas for purely business reasons, with no regard to whether the OPO can increase organ donation in those areas. For example, an OPO may wish to take over counties in a neighboring service area where hospitals demonstrate high conversion rates, which would improve the competing OPO's overall outcome performance measures but lead to no actual increase in organ donation. An OPO with a tissue bank may want a section of another OPO's service area that has particularly high tissue donation potential in hopes of expanding its tissue bank into the area. Because of the problems created by allowing competition for partial service areas, we believe it is critically important to require OPOs to compete for entire service areas.

If no OPO applied to compete for the service area of a de-certified OPO, we could select a single OPO to take over the entire open area or adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS would select an OPO based on the OPO's success in meeting the process performance standards during the preceding re-certification cycle

Competition When OPO Has Not Been De-Certified

We propose that all OPO service areas would be opened for competition at the end of every re-certification cycle. Once we determined that an OPO met the outcome measures at § 486.318 for the previous re-certification cycle and was found to be in compliance with the process performance measures and other requirements at §§ 486.320

through 486.348, CMS would open the OPO's service area for competition from other OPOs.

To compete for open areas, OPOs would be required to meet certain criteria based on data from the preceding re-certification cycle. An OPO would be required to meet the following: (1) 4 out of 5 outcome performance measures at or above the mean; and (2) a conversion rate of potential donors to actual donors at least 15 percentage points higher than the conversion rate of the OPO currently designated for the service area. (The conversion rate is the first of the five outcome performance measures.) OPOs would be required to compete for an entire service area. The incumbent OPO would be permitted to compete for its own service area.

To illustrate how this process would work, we provide the following example:

OPO A's service area is opened for competition. The OPO met 4 out of 5 outcome performance measures at or above the mean for the preceding re-certification cycle. Its conversion rate was 109 percent of the mean. A survey of the OPO determined that it met all process performance measures. Two OPOs would like to compete for OPO A's service area. Both OPOs met 4 out of 5 outcome performance measures at or above the mean and both met all process performance measures. OPO B's conversion rate was 117 percent of the mean, and OPO C's conversion rate was 125 percent of the mean. OPO C is permitted to compete for OPO A's open area because its conversion rate is 16 percentage points higher than OPO A's conversion rate. OPO B is not permitted to compete for the open service area because its conversion rate is only 8 percentage points higher than OPO A's conversion rate. In selecting an OPO for the service area, we would consider each OPO's success in meeting the process performance measures during the prior re-certification cycle, as well as submission of an acceptable plan to increase organ donation in the open service area.

We propose that an acceptable plan would, at a minimum: (1) Be based on the competing OPO's experience in its own service area; (2) include an analysis of existing barriers to increasing organ donation in the open area, both internal (for example, high staff turnover) and external (for example, language barriers due to a high number of recent immigrants in the OPO's service area); and (3) provide a detailed description of specific activities and interventions for increasing organ donation in the open area. An OPO's plan to increase organ donation in the open service area would be used by us to assist in identifying the most effective organization to maximize organ donation in the open area.

Given the constraints imposed by geography, as well as the variation in OPO performance, resources, and ability, we believe the process we propose would result in the selection of the OPO or OPOs most likely to improve organ donation rates in an open area.

As stated earlier in this preamble, we expect that our proposal would permit the competition process to be completed expeditiously. Agreements expire on July 31 of the year following the end of the re-certification cycle (for example, the current re-certification cycle ends December 31, 2005, and our agreements with OPOs expire July 31, 2006), giving us only 7 months to complete the many steps necessary to re-certify OPOs and renew their agreements with CMS. To reduce the uncertainty in the re-certification process identified by Congress, it is important that the competition process be completed as quickly as possible so that OPOs know whether they will retain their service areas for an additional 4 years.

We expect that the OPTN and SRTR will need a minimum of 2 months to finalize the OPO outcome performance measure data after the close of a re-certification cycle on December 31. This would leave at most 5 months for us to analyze the data, determine whether each OPO met or did not meet the requirements for re-certification, notify OPOs of their status, open service areas for competition, provide sufficient opportunity for OPOs competing for a service area (including the incumbent OPO) to develop and submit a plan to increase organ donation, review plans, designate an OPO for each service area that is under competition, notify OPOs of their status, and conduct transitional activities, as needed.

We believe that our proposed process would facilitate the timely completion of the competition for three reasons: (1) The process we propose is simple and straightforward; (2) the requirements we propose for OPOs to compete for an open area are unambiguous and, therefore, unlikely to lead to misunderstandings that could impede the process; and (3) the requirements for competition, as well as the prohibition against dividing service areas, would act to limit the number of OPOs permitted to or interested in competing for open areas.

We propose opening all OPO service areas at the end of every re-certification cycle because we believe that healthy competition between OPOs can lead to improvements in quality and outcomes, as long as there are strict criteria for selecting the OPOs that are permitted to compete for open areas.

We have found that completely unrestrained competition for OPO service areas can damage collaborative relationships, impede sharing of best practices across OPOs, and, as a result, degrade OPO quality. As a consequence of the Breakthrough Collaborative, OPOs have forged an impressive number of collaborative relationships. OPOs are eagerly sharing best practices and providing assistance to fellow OPOs in solving problems and reducing barriers to donation. For the first time, many OPOs are seeing themselves not just as individual businesses but as participants in a widespread campaign to save lives by increasing organ donation. We believe it is critical that the competition process we use to re-certify OPOs does not damage these collaborative relationships. Therefore, we are requesting comments on the following competition options.

One option would be a highly restricted competition process in which only service areas of OPOs that did not meet the conditions for coverage (that is, the outcome performance measures at § 486.318 or the process performance measures and other requirements at §§ 486.320 through 486.348) would be opened for competition. Any OPO that met the conditions for coverage would be re-certified, re-designated for its service area, and its agreement with CMS would be renewed for another 4 years. This competition process would considerably reduce the uncertainty in the re-certification process that was identified by Congress. However, this process would nearly eliminate desirable competition that we believe can create an incentive for OPOs to perform optimally.

We are soliciting comments on variations of the proposed limited competition process for OPOs whose service areas would be opened for competition at the end of a re-certification cycle (with the exception of OPOs whose service areas would be opened due to de-certification). Under these options, all service areas would be opened for competition, but the criteria OPOs would be required to meet to compete for open areas would differ. Under alternative one, an OPO would be permitted to compete for an open area if its conversion rate was a least 15 percentage points higher than the conversion rate of the OPO currently designated for the service area. This alternative would not require that an OPO meet a minimum outcome performance measure standard. It would allow more OPOs to compete for

open areas. However, this alternative would allow OPOs whose performance is below the mean to compete for open areas.

Alternative two is a limited competition process similar to the one we propose in this proposed rule, except that a competing OPO would be required to meet 120 percent of the mean, rather than 100 percent of the mean, for 4 out of 5 outcome performance measures. Under this alternative, an OPO still would be required to have a conversion rate at least 15 percentage points higher than the conversion rate of the OPO designated for the service area. It is likely that very few OPOs would be able to compete for open areas under this competition process, but the strict criteria would ensure that only the very best OPOs could compete for open areas.

We believe that the limited competition process we propose, if implemented, would encourage healthy competition that improves OPO quality and functioning and would lead to increased organ donation and transplantation. We are requesting comments on the proposed and alternative forms of competition in this proposed rule. Specifically, we are requesting comments regarding the effect of competition on increasing organ donation, especially in service areas of poorly-performing OPOs, and on the collaborative relationship among OPOs.

Proposed OPO Outcome Measures

[If you choose to comment on this section, please include the caption ''Outcome Measures'' at the beginning of your comments.]

Condition: Outcome Measures (Proposed § 486.318)

A. Current Outcome Performance Standards

Currently, five quantitative performance standards are used in evaluating OPO performance: number of donors, kidneys procured, kidneys transplanted, extra-renal organs procured, and extra-renal organs transplanted. Each of these outcome performance standards is calculated per million population, and OPOs are ranked accordingly. An OPO must be at or above 75 percent of the national mean for at least 4 out of 5 performance standards in order to be re-certified.

Congress directed that our new regulations include multiple outcome measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each OPO's service area. Many factors can affect the number of potential donors in a service area, such as a large elderly population, a low motor vehicle accident rate, or a high incidence of the Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS). These factors are likely to reduce the number of potential organ donors, whereas factors such as a high homicide rate or a high motor vehicle accident rate are likely to increase the number of potential donors.

B. Evaluation of Alternative Methods for Determining Organ Donor Potential

In a 1997 report, ''Organ Procurement Organizations: Alternatives Being Developed to More Accurately Assess Performance,'' the U.S. General Accounting Office (GAO) explored options for assessing OPO performance and recommended that CMS consider developing new outcome measures based on the number of potential donors in an OPO's service area. The report discusses the feasibility of replacing population with: (1) The number of deaths in an OPO's service area; (2) the number of deaths adjusted for age and cause of death; (3) an estimate of the number of potential donors in an OPO's service area determined by statistical modeling; or (4) the number of potential donors determined by death record reviews.

The GAO report noted that both the number of deaths and the number of deaths adjusted for age and cause of death are a better indicator of the number of potential donors than population because they eliminate a large portion of the population that an OPO cannot consider for organ donation. However, the GAO pointed out that there are significant drawbacks to using either deaths or deaths adjusted for age and cause of death, including lack of timely data and the inability to identify those deaths suitable for use in organ donation. For example, although the National Center for Health Statistics (NCHS) collects death data from States, Oklahoma, and Puerto Rico do not report their deaths, and there is an 18 to 24 month lag in the availability of death data from the NCHS.

The GAO recommended that CMS investigate the development of two different models for estimating the number of potential donors in an OPO service area. One of these models was developed by the Harvard School of Public Health and the Partnership for Organ Donation, and the other was developed under the auspices of the AOPO. Although death record reviews are acknowledged to be the ''gold standard'' for estimating the number of potential organ donors (as long as they are conducted with a standardized protocol by uniformly trained reviewers), they are, as the GAO noted, relatively labor intensive, time consuming, and expensive. Therefore, CMS concurred with GAO's recommendation to investigate alternatives for determining donor potential.

1. Regression Models for Estimating Donor Potential

Harvard and the Partnership for Organ Donation developed their model based on their 1993 study of 89 hospitals in 3 OPO service areas, using regression analysis to test hospital characteristics as predictors of the number of potential organ donors. Their analysis demonstrated that four hospital characteristics used together could be used to predict organ donation potential: Number of staffed beds, trauma center certification, medical school affiliation, and Medicare case-mix index (a measure of the complexity of cases treated in the hospital). The model was validated using death record reviews, and a study was conducted to verify the accuracy of the death record reviews (an interrator reliability study). The results of the study were published in the ''American Journal of Public Health'' in November 1998. (C Christiansen, S Gortmaker, J William, *et al.:* A Method for Estimating Solid Organ Donor Potential by Organ Procurement Region, American Journal of Public Health, Vol. 88, No. 22, November, 1998.)

Like the Harvard/Partnership model, the AOPO model was developed using regression analysis to test the validity of various hospital characteristics as predictors of donor potential. The AOPO model estimates the number of potential donors based on three factors: Whether the hospital has neurosurgery services; whether it has an emergency room; and whether it is a non-profit or for-profit entity. AOPO developed its model based on death record reviews in hospitals in 16 OPO service areas. (The study began with 30 OPOs, but 14 furnished incomplete data and their data were not included in many of the analyses AOPO used to develop its model.) An interrator reliability study to determine the accuracy of the OPOs' death record reviews has not been conducted.

In 1999, we contracted with the Harvard School of Public Health to apply the Harvard/Partnership model in all OPOs nationwide. In 2000, after receiving Harvard's results, we compared the number of potential

donors estimated by the Harvard model with the number of potential donors estimated by the AOPO model. (Both Harvard and AOPO used 1998 data.) We also compared the number of potential donors estimated by the two models in the 16 OPOs included in the AOPO study with the results from reviews of 1998 death records in those 16 OPOs' service areas conducted as part of the AOPO study. (Although AOPO has not conducted an interrator reliability study to verify the accuracy of the death record reviews, for purposes of this analysis, we assumed AOPO's death record reviews accurately estimated the number of potential donors in each OPO's service area during 1998.)

When compared to the number of potential donors determined by AOPO through death record reviews, neither the Harvard model nor the AOPO model consistently predicted the number of potential donors in individual OPO service areas. In AOPO's study of 16 OPOs, estimates ranged from 18.6 percent lower than the number of potential donors determined by death record reviews to an estimate that was 47.7 percent higher than the number of potential donors determined by death record reviews. The Harvard model's estimates ranged from 14.3 percent lower to 184 percent higher.

The failure of the two models to accurately estimate the number of potential donors may be due to many factors, including the accuracy (or inaccuracy) of information about hospital characteristics obtained by the researchers from a variety of sources, such as interviews with hospital staffs and American Hospital Association (AHA) data. Additionally, there were differences in criteria for hospitals' inclusion in the study between the original Harvard study and the CMS-contracted study, as well as differences between those studies and the AOPO study.

However, the primary reason the models produced such imprecise estimates is that they are based on regression analysis. Regression analysis is a method for estimating the statistical association between a group of independent (or predictor) variables and a dependent (or outcome) variable. Regression analysis can be used to test a hypothesis by determining how a change in one or more of the independent variables affects the value of the dependent variable. Both the Harvard and AOPO researchers tested the effect of a variety of hospital characteristics, such as number of full time equivalent positions (an independent variable) on the number of potential donors in a hospital (the dependent variable).

The development of a regression model involves: (1) Initial selection of variables that are believed to have predictive potential; (2) collecting and organizing the data on the chosen variables; (3) testing the correlation between the variables; (4) choosing independent variables with a low degree of correlation between themselves and a high degree of correlation with the dependent variable; and (5) validating the results against results obtained through a previously tested method (for example, through death record reviews). The objective is to develop a model that uses the least amount of independent variables necessary to have the greatest amount of predictive capability and which uses data that can be updated routinely from existing sources, such as AHA data. However, the model cannot be used indefinitely without revalidation to determine whether the independent variables remain predictive. Thus, in order to use the Harvard and AOPO regression models for certification purposes, they would have to be revalidated periodically using death record reviews.

Since they are based on regression analysis, both models produce an estimate of potential donors with a range (plus or minus) within which, statistically, there is a 95 percent probability that the true number of potential donors lies. This range is called the ''confidence interval.'' The range of the confidence interval is determined as illustrated in the following example. If the number of potential donors based on regression analysis is determined to be 100 and the confidence interval is 46, the range of the confidence interval is calculated by subtracting one half of the confidence interval from the number of potential donors (that is, one half of 46 is subtracted from 100 (100–23=77)) and adding one half of the confidence interval to the number of potential donors (that is, one half of 46 is added to 100 (100+23=123)). Thus, the range of the confidence interval in this example would be between 77 and 123, and one could be 95 percent certain that the number of potential donors was between 77 and 123.

The wider the confidence interval, the less certainty there is that the model works well as an estimate of the number of potential donors in a particular OPO's service area. Large intervals generally occur in OPO service areas with a small number of estimated potential donors or a small number of hospitals. In fact, Harvard has stated it does not believe its model produced an accurate estimate of the number of potential donors in eight OPO service areas that have only a small number of hospitals.

As an example, Harvard estimated that one small OPO had 96 potential donors in 1998, with a confidence interval width of 120; that is, one can be 95 percent confident that the actual number of potential donors was between 36 and 156. Similarly, AOPO estimated that a small OPO had 57 potential donors with a confidence interval width of 82; that is, one can be 95 percent confident that the actual number of potential donors was between 16 and 98. Obviously, it would be problematic to use estimates with such large confidence intervals for certifying OPOs.

However, even for large OPOs, the two models produce ranges that are unacceptably large for certification purposes. One of the largest of the 16 OPOs in the AOPO study was estimated to have 395 potential donors with an interval width of 93, that is, one can be 95 percent certain that the number of potential donors was between 349 and 442. Harvard estimated that the same OPO had 740 potential donors, with an interval width of 312, that is, one can be 95 percent certain that the number of potential donors was between 583 and 896.

Overall, the Harvard model estimates a much larger number of potential donors than the AOPO model for most individual OPO service areas. The Harvard model also estimates a much larger pool of donors nationwide than the AOPO model—11,700 to 21,800 potential organ donors annually to AOPO's 11,000 to 14,000 potential donors annually. It is certainly possible to debate the reasons for the disparities in estimates between the two models (both nationwide and in individual service areas). For example, the Harvard model was tested and validated in only 3 OPO service areas, whereas the AOPO model was tested and validated in 16 and, thus, may be more accurate. However, regardless of the reason for the difference in estimates of the number of potential donors between the two models, the central fact remains that they are unreliable estimates and, therefore, unacceptable for OPO certification purposes.

To demonstrate the effect of using those estimates to rate an OPO's performance, we can look at the large OPO that was estimated by the AOPO study to have 395 potential donors and use a hypothetical example to suppose that in 1998 the OPO had 180 donors, or a conversion rate (that is, the number of donors from whom organs are recovered for the purpose of

transplantation as a percentage of the number of potential donors) of approximately 46 percent. (The average conversion rate for the 16 OPOs in the AOPO study was 50 percent.) If, however, the OPO's actual number of potential donors was at the bottom of the confidence interval (349), its conversion rate was actually an above-average 52 percent, but if the actual number of potential donors was at the top of the confidence interval (442), its conversion rate was only 41 percent, which is well below average.

For smaller OPOs, the effect of the confidence interval is much greater, and could result in re-certification of a poor OPO or de-certification of a good OPO. For example, if we look at the small OPO estimated by AOPO to have 57 potential donors (with a confidence interval between 16 and 98 potential donors) and use a hypothetical example to suppose that it had 12 donors, its conversion rate based on its estimated potential of 57 donors is an abysmal 21 percent, and the OPO would very likely be de-certified. If the OPO's potential were at the top of the confidence interval (98 potential donors), the OPO looks even worse—with a conversion rate of only 12 percent. However, if the OPO's potential were at the bottom of the confidence interval (16 potential donors), its conversion rate would be an impressive 75 percent, and the OPO would be considered a top performer.

Our analysis of the Harvard and AOPO data showed that in some cases, as would be expected, the number of potential donors as determined by AOPO's 1998 death record reviews fell outside the confidence interval predicted by both models. Consider the example of one OPO estimated to have 192 potential donors using the AOPO model (confidence interval 152–232) and 197 potential donors using the Harvard model (confidence interval 135–259). According to AOPO's death record reviews, the OPO's actual number of potential donors was 130. Using a hypothetical example, we can suppose that the OPO had 65 donors in 1998. Thus, its conversion rate based on the AOPO death record reviews would have been 50 percent—average according to the AOPO study of 16 OPOs. However, according to the AOPO model, the OPO's conversion rate would have been only 34 percent; and according to the Harvard model, its conversion rate would have been 33 percent. With a threshold for re-certification established at 75 percent of the mean 50 percent conversion rate (37.5 percent), the OPO could have faced de-certification.

2. AOPO Recommendations

The AOPO has long been a champion of replacing population-based outcome performance standards with measures based on the number of potential donors. The goal of AOPO's death record review study was to find an alternative to population that would be a reasonably accurate measure of the number of potential donors. However, in a series of meetings with us to discuss the results of its death record review study, the AOPO did not recommend using either the AOPO or the Harvard methodologies to estimate donor potential in individual OPO service areas.

Instead, in written proposals to us dated February 28, 2001 and April 25, 2001, the AOPO recommended outcome measures based on both population and the number of potential donors as determined by death record reviews. AOPO's recommended outcome measures would consist of a two-tiered system for OPO certification that would rely on population in the first tier and, for OPOs that failed the first-tier measures, the number of potential donors determined by death record reviews in the second tier.

The AOPO recommended that we retain the 5 factors currently used to measure OPO performance, that is, donors, kidneys procured, kidneys transplanted, extra-renal organs procured, and extra-renal organs transplanted. They recommended that: (a) In the first tier, OPOs be screened using the current population-based performance standards, that is, OPOs would have to meet 4 out of the 5 current performance standards at 75 percent of the mean (2 performance standards at 50 percent of the mean for OPOs operating exclusively in non-contiguous States or territories) to pass the first tier; (b) an OPO not meeting the first-tier outcome measures be required by us to submit data for all deaths occurring in hospitals in its service area with 150 beds or more; (c) OPOs be re-certified if their death record review data indicated a conversion rate of at least 50 percent of the national mean conversion rate found in the AOPO study of 30 OPOs (including the 14 OPOs that furnished incomplete data); and (d) the national conversion rate be updated every 4 to 5 years.

C. Outcome Measures

1. Problems With Two-Tier Assessment

AOPO's recommended two-tier process relies primarily on population-based measures. In fact, the first tier is identical to the existing performance standards, and few, if any, OPOs would be assessed using second-tier measures based on death record reviews.

AOPO has criticized the current population-based performance standards because they fail to take into account factors that negatively impact the number of potential donors in an individual OPO's service area, such as high rates of HIV/AIDS and low motor vehicle accident and homicide rates. They argue that population-based measures cause some good OPOs to look like poor performers. However, the reverse is also true—factors in some OPO service areas, such as low rates of HIV/AIDS and high motor vehicle accident and homicide rates, may create a relatively high donor potential, making OPOs whose actual performance is below average look like good performers.

The implications of this are clear. The two-tier method might prevent de-certification of good OPOs by giving OPOs that may be disadvantaged by population-based measures an opportunity to prove they are good performers by submitting results from death record reviews. However, the two-tier method would not prevent re-certification of poorly performing OPOs that may appear to be good performers using population-based measures.

In the congressional findings associated with section 219 of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554), Congress directed the Secretary to develop measures that ''accurately measure performance differences among the organ procurement organizations.'' We do not believe a two-tier method with the first tier based on population is a reliably accurate methodology for assessing OPO performance, and we do not believe re-certification of OPOs should be based on an inaccurate methodology. Furthermore, we believe it is incumbent upon the agency, as both a prudent purchaser of health care services and a guardian of the organ donation system in the United States, to propose an accurate measure of OPO performance ''based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations,'' as Congress clearly intended in 42 U.S.C. 273(b)(1)(D)(ii). Such a measure should enable the Secretary and the public to distinguish between good OPOs and poor OPOs.

In addition to its reliance on population-based measures in the first tier, another drawback of the two-tier process proposed by AOPO is that in order to use death record review results in the second tier, we initially would

need to calculate a national conversion rate to which OPOs could be compared and then recalculate the conversion rate periodically—probably every 4 to 5 years. AOPO has suggested that we determine the national conversion rate through a sample of death records from hospitals throughout the United States. We believe this process would go far beyond the ''reasonable effort'' Congress envisioned for determining donor potential.

Furthermore, in order to have the national conversion rate available to us shortly after the close of a re-certification cycle, a national sample would have to be calculated well in advance of the end of the re-certification cycle to allow us sufficient time to find a contractor and to allow the contractor sufficient time to design and conduct a study and analyze the results. However, if all OPOs passed the first tier at the conclusion of the re-certification cycle, CMS would have no need of the national conversion rate that it had obtained. We believe there is a simpler, more accurate, and more reliable method of measuring an OPO's performance according to its donor potential.

2. OPTN Data as Alternative Data Source

We propose eliminating the use of population-based standards and, instead, basing outcome measures entirely on organ donor potential. Organ donor potential (that is, the number of potential organ donors) would be determined by data reported by OPOs to the OPTN, based primarily on referral calls the OPOs receive from hospitals. We believe this system would be simple, straightforward, and easy for OPOs and the public to understand. Furthermore, the OPOs already report data on organ donor potential to the OPTN.

OPOs report certain data elements to the OPTN whenever they query the OPTN's system to find a match for a potential donor, and the OPTN has a sophisticated system in place to capture this information electronically. As part of its efforts to monitor the impact of the hospital CoP (condition of participation) for organ, tissue, and eye procurement), the Health Resources and Services Administration (HRSA) asked the OPTN in 2001 to begin collecting additional, hospital-specific data from OPOs, including the number of referral calls OPOs receive from hospitals reporting deaths and imminent deaths, the number of referrals meeting organ donor eligibility criteria (that is, the number of potential donors), and the number of consents obtained on referrals meeting organ donor eligibility criteria. Data are reported monthly for deaths occurring during the previous month. The data are obtained by the OPOs from referral calls hospitals and critical access hospitals are required to make to OPOs by the hospital CoP (see §§ 482.45 and 485.643) and are supplemented by data gathered by OPOs onsite at their hospitals. OPOs began reporting the data to the OPTN in September 2001.

In the first few months of the data collection, HRSA and the OPTN found many instances of incomplete data reporting by the OPOS, particularly the number of deaths and imminent deaths. However, the completeness of these data is improving. OPOs reported approximately 900,000 deaths and imminent deaths in 2002 (a known undercount), which is not far from the 982,914 inpatient hospital deaths reported by the National Center for Health Statistics for 2000. The number of potential donors reported by OPOs (termed ''eligible deaths'' by the OPTN and SRTR) for 2002 is consistent with estimates of the annual number of potential donors made by the organ donation community. HRSA and the OPTN continue to work with OPOs to further improve the database. We expect that if these data are used for certification purposes, the completeness of the data will approach 100 percent.

To assess the accuracy of the data OPOs are reporting to the OPTN, the SRTR recently analyzed the ability of ''eligible deaths'' data to predict the actual number of donors. They compared ''eligible deaths,'' as well as the number of potential donors estimated by the Harvard model with the actual number of donors. The researchers found ''eligible deaths'' to be substantially more predictive of actual donors. The SRTR noted that more complete data reporting by OPOS to the OPTN will improve the reliability of the data. (''New Methods for Estimating Total Potential (Organ) Donors in the U.S.'' J McGowan, M Guidinger, R Pietroski, D Gaylin, A Ojo, *et al.* Abstract presented at American Transplantation Congress meeting, Washington DC, May 30–June 4, 2003.)

3. Standardized Definition of Organ Donor Potential

Our proposed definition is based on patient age, cause of death, and co-morbid conditions that contraindicate donation. We would use the following definition of ''organ donor potential'': the number of patients whose age is 70 or less meeting death by neurological criteria, based on generally accepted practice parameters for determining brain death, who do not have any of the following clinical indications:

- Tuberculosis.
- Creutzfeldt-Jacob disease or any other prion-induced disease.
- Viral septicemia.
- Rabies.
- Reactive hepatitis B surface antigen.
- Any retro virus infection.
- Active malignant neoplasms, except primary central nervous system tumors and basal cell and squamous cell carcinomas.
- Aplastic anemia.
- Agranulocytosis.
- Active viral and systemic fungal infections.
- Gangrene of bowel.
- Extreme prematurity.
- Positive serological or viral culture findings for HIV.
- Chagas Disease.

Although the upper age limit for donation continues to rise as OPOs and transplant programs become increasingly willing to consider recovering and transplanting ''expanded criteria'' organs, almost all organs come from donors younger than 70. Therefore, we propose limiting the definition of ''organ donor potential'' to donors of age 70 and below. We propose limiting the definition to include only deaths from neurological causes (that is, brain death) rather than including non-heartbeating donation (also called donation after cardiac death (DCD)). Although DCD is becoming more common, it remains the exception; in 2000, there were only 119 non-heartbeating donors, and in 2001, there were only 167. We are proposing rule-out criteria that are generally accepted by the organ donation and transplantation community as precluding organ donation because these co-morbid conditions render an individual medically unsuitable for organ donation. However, we are specifically requesting public comments regarding our proposed definition.

We propose using a specific term, ''potential donor denominator,'' for the data on organ donor potential OPOs would report to the OPTN. The potential donor denominator would indicate the number of individuals in an OPO's service area who meet the criteria for organ donor potential, as defined by regulations. The term ''potential donor denominator'' would differentiate the data OPOs would report to the OPTN from data based on other definitions of ''potential donor'' or ''organ donor potential'' used in the OPO community.

Because definitions vary among OPOs, the universe of potential donors we would use for OPO certification could be different from that used by some OPOs. For example, an OPO that

has liberal donor criteria (perhaps including recovery of non-heartbeating donors) would consider itself to have a larger number of potential donors than the number it reports to the OPTN for the ''potential donor denominator.'' In these instances, OPOs would be able to exceed 100 percent of the standard. Conversely, an OPO with conservative donor criteria would consider itself to have a smaller number of potential donors than the number it reports to the OPTN.

Determining whether organs should be recovered and transplanted is a medical decision; therefore, our proposed definition is not intended to limit the donors or organs an OPO recovers for transplantation. We are aware that many OPOs are successfully recovering transplantable organs from donors that do not fall within our proposed definition.

4. OPTN Data

In outlining the limitations of the current re-certification process, Congress noted that outcome and process performance measures should be considered that would ''more accurately reflect the relative capability and performance of each organ procurement organization.'' We believe that basing multiple outcome measures on potential donor denominator data reported to the OPTN, as we propose, would give us, each OPO, the organ donation and transplantation community, and the public a clear picture of OPO capability and performance and eliminate possible inaccuracies and inconsistencies associated with current population-based standards.

Using potential donor denominator data reported to the OPTN would have additional significant advantages. Congress required the Secretary to propose standards based on ''empirical evidence, obtained through reasonable efforts'' of organ donor potential. Thus, we believe that Congress expected that the outcome measures data would be verifiable and that the processes used to obtain and verify the data would be practical and sensible.

The SRTR has developed a methodology that is being used to validate the data OPOs report to the OPTN. The methodology is based on readily available data on hospital bed size and other factors, as well as hospital death data obtained from the National Center for Health Statistics. If data reported by an OPO appear to be incorrect, the SRTR performs further analysis, and the data is corrected if necessary. We are confident that the use of this methodology would ensure that the data used for OPO certification are accurate.

OPTN data also would be verified by hospital surveyors when they review data on hospital deaths and hospital death records to verify hospital and critical access hospital compliance with the CoPs. In addition, since we propose requiring OPOs to publish hospital-specific organ donation data annually (see proposed § 486.328), hospitals could verify their own data to ensure OPOs are reporting data accurately to the OPTN. Certainly, using OPTN data would be both sensible and practical because the OPTN already has a system in place to collect and verify the data, and all 59 OPOs have the capability to report the data electronically.

5. Death Record Reviews as Alternative Data Source

Because death record reviews are considered by the OPO community to be the ''gold standard'' for estimating the number of potential donors in a hospital, we considered proposing outcome measures based entirely on data derived from OPOs' reviews of hospital death records. GAO gave serious consideration in its 1997 report to the use of death record reviews performed by OPOs to determine the number of potential donors for OPO certification. However, there are a number of disadvantages to basing certification on death record review data. In fact, the GAO report noted drawbacks to using OPO-conducted death record reviews, including the cost of the reviews and the challenge of maintaining consistency in the reviews.

Maintaining consistency in performing death record reviews for certification purposes would be difficult, because we would have to ensure that all 59 OPOs performed the reviews in the same manner. This would require development of a standardized protocol for the reviews, as well as ongoing, nationwide training for OPOs in hospital selection, sampling, record review, and reporting. Furthermore, it would be difficult for many OPOs to complete death record reviews for the final year of the re-certification cycle in time for us to use the data for re-certification. (Note that while we propose requiring all OPOs to perform death record reviews as part of their QAPI programs (see proposed § 486.348), death record reviews performed by OPOs for their own purposes would not require standardization across OPOs because the reviews would be performed solely to provide data for quality improvement for each individual OPO.)

Therefore, in weighing the two methods of determining the number of potential donors (data reported by hospitals to OPOs and by OPOs to the OPTN or death record reviews performed by OPOs), we believe that using OPTN data most clearly fulfills Congress's intention in requiring promulgation of measures based on ''empirical evidence, obtained through reasonable efforts.'' OPTN data would provide an accurate measure of organ donor potential and OPO performance, and using OPTN data would be simple and straightforward because a system is already in place to report, capture, and disseminate the data.

We propose that potential donor denominator data reported to the OPTN to be used for OPO re-certification include data for all deaths that occur in Medicare and Medicaid participating hospitals in an OPO's service area, unless a hospital has received a waiver to work with a different OPO. At present, OPOs are reporting data to the OPTN within 30 days of the end of the month in which a death occurred, and we propose requiring that OPOs continue to report their data within this time frame. We believe this provides adequate time for OPOs to report data, while ensuring that data will be available to us when needed for certification purposes. (This proposal can be found in the proposed condition for reporting of data at § 486.328(b).)

To ensure accuracy, OPOs would need to report the potential donor denominator data consistently, adhering strictly to the criteria in the proposed definition for organ donor potential. Reporting the data ''consistently'' means that if the OPO determined at any time, from the referral of a patient by a hospital through recovery and testing of the patient's organs, that the patient met any of the rule-out criteria listed in the definition, the patient would be eliminated as a potential donor and would not be reported to the OPTN under this regulation. If an OPO determined through death record reviews or other means that the potential donor denominator data it reported to the OPTN was incorrect, the OPO would be required to report the corrected data to the OPTN within 30 days of the end of the month in which the mistake is identified. (This proposed requirement can be found in the proposed condition for information management at § 486.328(b).)

However, while we propose basing OPO outcome measures on the number of potential donors as evidenced by OPTN data, we are specifically requesting comments on the feasibility of basing OPO outcome measures on the

number of potential donors as determined by death record reviews.

6. Outcome Performance Standards and Thresholds

With the exception of OPOs operating exclusively in non-contiguous U.S. States, territories, possessions, or commonwealths, we propose an OPO certification threshold of 75 percent of the national mean for 4 out of 5 of the following outcome measures, averaged over the 4 calendar years before the year of re-certification: (1) Donors as a percentage of the potential donor denominator; (2) number of kidneys procured, as a percentage of the potential donor denominator; (3) number of kidneys transplanted, as a percentage of the potential donor denominator; (4) number of extra-renal organs procured, as a percentage of the potential donor denominator; and (5) number of extra-renal organs transplanted, as a percentage of the potential donor denominator.

These five OPO performance factors are the same as those used in the current outcome performance standards. However, the outcome performance measures we propose would be based on the organ donor potential in an OPO's service area, rather than the population in the service area. We are proposing the same performance factors because they represent the totality of what an OPO does—from identifying and managing potential donors through ensuring delivery of healthy organs to hospitals for transplantation.

An OPO operating exclusively in non-contiguous States, territories, possessions, or commonwealths would be required to meet the following outcome measures at 50 percent or more of the national mean, averaged over the 4 calendar years before the year of re-certification: (1) Number of kidneys procured, as a percentage of the potential donor denominator; and (2) number of kidneys transplanted, as a percentage of the potential donor denominator. As in the current regulations, OPOs operating in non-contiguous areas would be required to meet measures only for kidneys procured and kidneys transplanted because there are few extra-renal transplant programs located in non-contiguous areas and because the permissible cold ischemic time for extra-renal organs is shorter than that for kidneys, making shipment of extra-renal organs to the continental U.S. for transplantation problematic.

We believe all 5 proposed outcome measures are critical for assessing performance of OPOs located in the continental United States because, taken together, they reflect the entire spectrum of the donation process for which those OPOs are responsible. Furthermore, although it is true that organs recovered by an OPO for transplantation sometimes are discarded (or used for research instead of transplantation) for reasons beyond the control of the OPO, OPOs are responsible for the majority of functions that determine whether an organ is transplanted (for example testing, recovery of the organ, packaging, and transport). Nevertheless, since there is some disagreement in the OPO community on this issue, we are specifically requesting public comments on the need for each of the five measures.

Under current regulations, OPOs report outcome performance data to us only for pancreata procured for whole organ transplantation. However, legislation enacted on October 25, 2004 (Pub. L. 108–362) which amends section 371 of the PHS Act, requires that pancreata recovered and used for islet cell transplantation or for research be counted for purposes of OPO certification and re-certification. Therefore, when compiling outcomes performance measures data and utilizing the data for re-certification of OPOs, we will include pancreata recovered and used for islet cell transplantation or for research under the category of extra-renal organs, along with pancreata recovered and used for whole organ transplantation. Also, because researchers and OPOs have suggested that we encourage OPOs to recover other organs for research purposes, we invite comment on whether all organs recovered for research should be included in the outcome measures.

When the current outcome performance standards were established, we deliberately set the threshold for re-certification at a point we thought would prevent de-certification of good OPOs based on what may have been imprecise population-based performance standards. It would seem logical that along with adopting more precise outcome measures, we would raise the threshold for re-certification. However, since measures based on a potential donor denominator have never been used for OPO certification, we are somewhat reluctant to propose a change in the threshold for re-certification that might result in the de-certification of many OPOs. Nevertheless, we are specifically requesting public comment on the following three issues: (1) Whether OPOs located in the continental U.S. should be required to meet more (or less) than 75 percent of the national mean and, if so, the appropriate percentage threshold; (2) whether OPOs operating in non-contiguous states or territories should be required to meet more (or less) than 50 percent of the national mean; and (3) whether OPOs located in the continental U.S. should be required to meet all 5 (instead of just 4) measures.

OPO Process Performance Measures

Condition: Participation in Organ Procurement and Transplantation Network (Proposed § 486.320)

Current OPO regulations at § 486.308 require OPOs to be members of and abide by the rules of the OPTN, and we propose to retain this requirement. However, we propose eliminating the requirement for an OPO to become an OPTN member before becoming designated by us because the OPTN requires an OPO to furnish information demonstrating designation by us to become a member of the OPTN. (See 42 CFR 121.3(b)(2).) Therefore, we propose that only after being designated would an OPO be required to be a member of the OPTN. In addition, we propose to eliminate the requirement that OPOs have a written agreement with the OPTN because a written agreement is not part of the OPTN membership process.

Condition: Relationships With Hospitals, Critical Access Hospitals, and Tissue Banks (Proposed § 486.322)

[If you choose to comment on this section, please include the caption ''Relationships with hospitals'' or ''Relationships with tissue banks'' at the beginning of your comments as appropriate.]

Good relationships between OPOs and organizations involved in the donation process often result in more efficient operations, such as shared referral lines for hospitals to use when calling about deaths and collaboration between OPOs and tissue banks in training hospital designated requestors. Furthermore, collaboration and cooperation between donation organizations promotes a positive public opinion about donation.

All six OPOs whose practices were studied for the Organ Donation Breakthrough Collaborative have strong collaborative relationships with their hospitals. Donor Alliance in Colorado has 6 full-time ''donation consultants,'' who are liaisons to the 100 hospitals in the OPO's service area and provide professional education and feedback. In-house coordinators from LifeGift Organ Donation Center in Houston meet regularly with hospital medical staff to

review organ donation cases. The University of Wisconsin OPO ''views hospital staff as an extension of OPO staff, contributing to the achievement of OPO goals.'' Their OPO staff encourage physicians, nurses, and pastoral care staff to participate in the donation process and provide support and guidance.

Collaboration between OPOs and hospitals is absolutely critical to the donation process. Good relationships encourage cooperation from hospital staffs in making referrals of potential donors timely, supporting OPOs in discussing donation with families (or acting as designated requestors), and providing support services for management of potential donors. We expect that the requirements we propose will increase communication and cooperation between OPOs and the hospitals in their service areas.

The current regulations at § 486.306(g) require OPOs to have a working relationship with at least 75 percent of the Medicare and Medicaid participating hospitals in their service areas that have an operating room and the equipment and personnel for retrieving organs. Regulations at § 486.304(b)(8) require OPOs to have a working relationship with any hospital in the service area, including a transplant hospital that requests a working relationship. Furthermore, the hospital and critical access hospital CoPs for organ, tissue, and eye procurement require all Medicare and Medicaid participating hospitals and critical access hospitals to have and implement an agreement with an OPO designated under part 486 that includes a protocol for referral of all deaths and imminent deaths. (See §§ 482.45 and 485.643.)

We considered proposing a rule that would require an OPO to have an agreement with every hospital and critical access hospital in its service area (unless a hospital had a waiver to work with a different OPO) to ensure that OPOs do not overlook a single potential donor. However, the PHS Act requires only that an OPO have agreements with a ''substantial majority'' of hospitals in its service area that have facilities for organ donation.

Therefore, we propose maximizing the number of hospitals with which OPOs have agreements (consistent with the PHS Act) by requiring OPOs to have agreements with 95 percent of the hospitals and critical access hospitals in their service areas that have both a ventilator and an operating room. (**Note:** If a hospital received a waiver from us to work with another OPO, the hospital would not be counted as part of the OPO's service area.) Since it is necessary for a hospital to have a ventilator to maintain a potential donor and an operating room for recovery of organs, we believe a requirement for OPOs to have agreements with 95 percent of hospitals and critical access hospitals with a ventilator and an operating room would capture a ''substantial majority'' of hospitals with facilities for organ donation.

Our OPO Coordinators have found that most OPOs ask their hospitals to sign a ''generic'' agreement that does not address each entity's role in the donation process and does not define key terms, such as ''imminent death'' and ''timely referral.'' This lack of specificity can lead to problems; for example, disagreement between an OPO and hospital about their respective roles in discussing donation with families, differing viewpoints of OPO staff and hospital physicians regarding what constitutes ''imminent death,'' or disagreements between an OPO and hospital about the appropriate timing of referrals to the OPO. However, the Coordinators have observed that where OPOs network with their hospitals to clearly define roles and responsibilities for the donation process, referral rates are higher.

Therefore, to avoid problems, promote collaboration, and assure that OPOs' agreements with their hospitals support the overall goal of maximizing organ donation and transplantation, we propose requiring that OPOs' agreements with hospitals and critical access hospitals must describe the responsibilities of both the OPO and the hospital in regard to the hospital requirements at §§ 482.45 or 485.643, as appropriate, (for example, how referrals will be made and how collaboration in reviewing death records will occur) and specify the meaning of the terms, ''timely referral'' and ''imminent death.''

One of our proposals for OPOs' relationships with their hospitals is based on observations made by the Office of the Inspector General (OIG) in its August 2000 report on the hospital CoP. The OIG noted that although research shows that collaboration between OPOs and hospitals in approaching families about organ donation yields the highest consent rates, the OIG found that 23 out of 61 OPOs had not provided any training to hospital staffs. Only 22 OPOs had trained designated requestors in more than 10 percent of the hospitals in their service areas. (A ''designated requestor'' under the hospital CoP is an individual who has been trained in a course offered or approved by the OPO to discuss donation with families of potential donors. See § 482.45(a)(3).)

The OIG estimated that 70 percent of hospitals had been offered designated requestor training by their OPOs; however, staff in only 44 percent of hospitals had been trained. The OIG suggested this could be due to ''a number of practices that indicate OPO resistance to training and using hospital staff as designated requestors.'' They noted that some OPOs make it difficult for hospitals staffs to attend training (for example, holding training sessions several hundred miles away from hospitals), and other OPOs establish programs that lack the flexibility to respond to the needs of various types of hospitals and individuals.

Although CMS intended the designated requestor requirement in the hospital CoP to lead to more collaboration between OPOs and hospitals and increased hospital involvement in the donation process, the OIG commented that the requirement may have had the opposite effect. That is, since OPOs are reluctant to train hospital staffs and to involve them in the donation process, some hospitals are allowing OPOs to take over the entire donation process.

Nevertheless, in some OPO service areas, the OPO handles most or all requests for donation, and consent rates are good. In other areas, hospitals cannot spare staff to attend designated requestor training, and the hospital and critical access hospital CoPs makes it clear that the hospital, not the OPO, has the right to decide whether an OPO representative or a hospital designated requestor will offer the option of donation. Based on these facts, we do not believe it would be advisable to require every OPO to provide designated requestor training in every hospital and critical access hospital in its service area. Instead, we propose requiring OPOs to offer designated requestor training on at least an annual basis for hospital and critical access hospital staffs. We propose that training be offered at least annually because most hospital staff do not discuss donation with families frequently enough to maintain their proficiency unless they receive periodic training.

We urge OPOs to encourage designated requestor training so that hospital staff can support and collaborate with OPO staff in the donation process. We applaud the efforts of OPOs like LifeLine of Ohio that actively promote designated requestor training in hospitals. In its ''Quest for Excellence'' in educating hospitals, LifeLine made it possible for staff in those hospitals to earn free

continuing education credits by completing designated requestor training, either in the hospital or via the Internet. In the University of Wisconsin OPO service area, hospital staff are the primary requestors. OPO staff conducts a designated requestor training program and ongoing training and case reviews at hospitals to educate hospital staff about all aspects of organ donation, including case management.

Before the CoP, hospitals called tissue banks about potential tissue donors and called OPOs about potential organ donors. However, the hospital CoP at § 482.45 and critical access hospital CoP at § 485.643 require hospitals and critical access hospitals to refer all deaths and imminent deaths (rather than just potential organ donors) to an OPO. The hospital and critical access hospital CoPs state that in the absence of alternative arrangements between a hospital and a tissue bank, the OPO will determine suitability for tissue donation. However, after the hospital CoP went into effect in August 1998, very few hospitals were willing to have ''alternative arrangements'' that would have required them to call tissues banks about potential tissue donors in addition to calling an OPO about every death. Thus, in most areas of the country, OPOs became the ''gatekeepers'' for information about potential tissue donors. Since many OPOs are in the tissue banking business, the OPOs' gatekeeper position created some tension between a few OPOs and the independent tissue banks in their service areas.

We have received complaints both from tissue banks and OPOs. Tissue banks have charged that OPOs fail to notify them about potential tissue donors in a timely manner, charge unreasonable referral fees for notifying them of potential donors, refuse to allow tissue banks to participate in designated requestor training sessions OPOs provide to hospitals, or refuse to use the tissue banks' screening and notification protocols when referring donors.

For their part, OPOs have complained that some tissue banks have paid no referral fees since the hospital CoP went into effect in August 1998. (We require OPOs to charge tissue banks for their costs in making referrals so that the costs are not passed on to the Medicare program. (See Medicare Provider Reimbursement Manual, section 2773.1)) In addition, some OPOs have charged that tissue banks do not respond timely to the referrals they receive, resulting in the loss of viable tissue. Since donor families and the public often regard all donation as organ donation, that loss of donation potential in a donor for whom consent has already been obtained may reflect badly on the OPO, rather than the tissue bank.

Clearly, difficult relationships between OPOs and the tissue banks in their service areas waste valuable time and energy and distract OPOs from their mission of maximizing organ donation. Therefore, based on the Secretary's authority under section 1102 of the Act to establish requirements necessary for the efficient administration of the Medicare program, as well as the PHS Act requirement at section 371(b)(3)(I) for OPOs to ''cooperate'' with tissue banks to ensure all usable tissues are obtained, we are proposing requirements to ensure that OPOs maintain collaborative relationships with the tissue banks in their service areas. We believe the requirements we propose would serve to promote cooperation on the part of OPOs.

We propose to strengthen the current requirement for OPOs to cooperate with tissue banks in the retrieval, processing, preservation, storage, and distribution of tissues, as may be appropriate, to ensure that all usable tissues are obtained from potential donors. We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors:

(1) Screening and referral of potential tissue donors;

(2) Obtaining informed consent from families of potential tissue donors in the absence of a donor document; and

(3) The retrieval, processing, preservation, storage, and distribution of tissues.

An OPO would not be required to have an arrangement with a tissue bank unwilling to have an arrangement with the OPO. In such a situation, we would not consider the OPO to be out of compliance with the requirement.

It should be noted here that the goal of the Secretary's Donation Initiative is to increase all types of donation, including tissue, marrow, and blood donation. Therefore, although the purpose of this proposed rule is to increase organ donation, the Secretary has an interest in ensuring that OPOs act responsibly and collaboratively to further tissue donation in the United States.

Condition: Administration and Governing Body (§ 486.324)

[If you choose to comment on this section, please include the caption ''Administration and governing body'' at the beginning of your comments.]

In the current regulations, requirements for OPO boards are found at § 486.306, which lists qualifications to be designated by us as an OPO. We propose creating a separate section for administration and governing body, which would contain the proposed requirements for membership composition and bylaws of OPO boards, as well as requirements for the governing body that would have legal authority and responsibility for the management and provision of OPO services.

Section 371(b)(1)(G) of the PHS Act (42 U.S.C. 273(b)(1)(G)) stipulates that a qualified OPO must have a board of directors or an advisory board that is composed of:

- Members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area;
- Members who represent the public residing in such area,
- A physician with knowledge, experience, or skill in the field of histocompatibility;
- A physician with knowledge or skill in the field of neurology; and
- A surgeon from each transplant center in the OPO's service area with which the OPO has arrangements to coordinate its activities. (The surgeon must have practicing privileges in the represented transplant center and perform organ transplant surgery).

In addition, the PHS Act states the board has the authority to recommend policies for the procurement of organs and other functions (which are described below) and has no authority over any other activity of the OPO.

The current regulations at § 486.306(f) require an OPO to have a board of directors or an advisory board. An OPO may have more than one board, but at least one board must be responsible for recommending policies relating to the donation, procurement, and distribution of organs and include the specific membership composition required by the PHS Act. (See section 371(b)(1)(H) (42 U.S.C 273(b)(1)(H).)

We are proposing a similar requirement, in that an OPO may have as many individual boards as it chooses, but one of its boards must have the specific membership composition prescribed by the PHS Act and must operate under restraints similar to those prescribed by the PHS Act for that board. That is, the board would be limited to recommending policies relating to the donation, procurement, and distribution of organs, would serve

only in an advisory capacity, and could not also serve as the OPO's board of directors. For purposes of discussion in this preamble, we refer to this board as an advisory board. To ensure that the board's members remain in an advisory capacity as stipulated by the PHS Act, we propose that the board's members would be prohibited from serving on any other OPO board. We also would require OPOs to have bylaws for each of its boards to address potential conflicts of interest, length of terms, and criteria for selection and removal of members.

Note that there appears to be a cross-reference problem in the PHS Act related to the recommendations of the advisory board. The statute provides that the advisory board ''has the authority to recommend policies for the procurement of organs and other functions described in (2). (See 42 U.S.C 273(b)(1)(H)(ii).) Currently, section 371(b)(2) is directed to the Secretary and concerns rulemaking. It does not speak to policies where an advisory board's recommendations would be relevant for an OPO. We believe it is likely that Congress intended that the OPO obtain the recommendations of the advisory board on the functions that an OPO is required to perform and that are listed in section 273(b)(3). We are proposing that the advisory board make recommendations to the OPOs on the subjects discussed in section 273(b)(3) and that are specifically listed in proposed § 486.324(b) through (11). Even if there were not a cross-reference problem, we would propose that the advisory board make recommendations to the OPO on the topics identified in our proposed rules based on our authority at 42 U.S.C. 1102. The expertise of the board would provide a useful perspective on those issues, and the advisory board's recommendations would likely lead to more efficient and effective actions by the OPO in procuring organs, as well as better coordination with various business partners.

We propose including in the condition for administration and governing body, certain language from the PHS Act that specifies the types of policies this advisory board can recommend. We believe that it is worth restating these specific provisions, both because the philosophy behind them is important and because we do not believe all OPOs and OPO board members are aware of them.

The single OPO advisory board whose membership composition is mandated by the Act has the authority to recommend policies for the procurement of organs and other functions including: (1) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation; (2) systematic efforts, including professional education, to acquire all usable organs from potential donors; (3) arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome; appropriate tissue typing of organs; a system for allocation of organs among transplant patients according to established medical criteria; transportation of organs to transplant hospitals; coordination of activities with transplant hospitals in the OPO's service area; participation in the OPTN; arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to ensure that all usable tissues are obtained from potential donors; annual evaluation of the effectiveness of the OPO in acquiring organs; and assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors. The PHS Act states that the OPO board ''has no authority over any other activity of the organization.'' (See section 371(b)(1)(H)(iii) of the PHS Act (42 U.S.C. 273(b)(1)(H)(iii).)

It has come to our attention that some OPO boards with the membership composition stipulated by the PHS Act may do more than recommend policies. This is a matter of concern because some OPOs have told us that their boards prevent them from taking steps to adopt best practices because of the costs involved (for example, by refusing to approve the hiring of additional staff or implementation of protocols to provide better management of potential donors). Board members may be motivated by a desire to keep standard organ acquisition fees low for the transplant hospitals in their OPO's service area; however, the result may be that organ donation rates remain low as well. We would note that some OPOs have taken steps to address what they regard as the conflict of interest created by having a board heavily weighted with representatives of transplant centers. For example, New England Organ Bank (one of the high-performing OPOs studied in the Organ Donation Breakthrough Collaborative) has balanced the representation on its board by adding members to its board who represent other hospitals and community interests. Donor alliance, another OPO studied by the Collaborative, has a 25-member community-based board that has ''allowed considerable latitude for innovation and risk-taking.''

By incorporating this language into our proposed regulations for OPOs, we are reminding OPOs and their boards that under the PHS Act, the OPO board whose membership composition is outlined in the PHS Act has specific limits placed on its authority.

Note that our proposed language differs from that of the PHS Act in some respects. Instead of ''a system for allocating organs according to established medical criteria'' we propose referencing ''a system for allocating organs according to the rules and requirements of the OPTN,'' because the OPTN establishes the medical criteria used to allocate organs among transplant patients. (The term ''rules and requirements of the OPTN'' means those rules and requirements approved as enforceable by the Secretary.)

Both the PHS Act and the existing regulations require an OPO to have a tissue bank representative on its board. We propose requiring an OPO to have on its advisory board a tissue bank representative from a facility not affiliated with the OPO, unless the only tissue bank in the service area is affiliated with the OPO. (In other words, if the OPO operates a tissue bank, the OPO must include an independent tissue bank on the board that represents all independent tissue banks in the OPO's service area, unless there are no independent tissue banks in the OPO's service area.) These requirements presume that tissue bank representatives with these qualifications exist in an OPO's service area and would be willing to serve on the OPO's advisory board. If not, the OPO would not be considered out of compliance with this requirement.

Because of the ''gatekeeper'' role of OPOs in regard to potential tissue donors, we believe it is important for OPO boards to include representatives from tissue banks that are not affiliated with the OPO (unless, of course, the OPO has the only tissue bank in the service area) to ensure that tissue banks have some voice in the OPO policies that affect them and to encourage OPOs and tissue banks to work together on issues that affect both organizations.

Although the PHS Act specifies that hospital administrators must be

represented on an OPO's board of directors or advisory board, it does not specify whether donor or transplant hospital administrators should be represented. Since transplant hospitals are already well represented by the many transplant surgeons who serve on OPO boards, we strongly urge (but would not require) OPOs to include administrators from donor hospitals to provide input and foster collaboration between OPOs and their donor hospitals.

We have received suggestions that we require OPOs to include representatives from research facilities, donor family members, transplant recipients, coroners or medical examiners, social workers, and chaplains on their advisory boards. Although these are worthy suggestions, we are reluctant to require OPO advisory boards to accommodate all these interests, lest they become too large to operate effectively. Additionally, many OPOs already include some of these individuals on their boards to fulfill the requirement for members representing the public. Therefore, we are requesting comments on the advisability of requiring OPO boards to have those representatives.

Note that, for clarification purposes, we are proposing to change the current requirement for an OPO to have a transplant surgeon from each transplant center on its board to a requirement for an OPO to have a transplant surgeon from each transplant hospital on its advisory board. Although ''transplant hospital'' and ''transplant center'' are often used interchangeably, the term ''transplant center'' sometimes is used to refer to an individual transplant program (such as a heart transplant program or liver transplant program) within a hospital that performs transplants. Since some OPOs have more than a dozen transplant hospitals in their service areas, a requirement to have a transplant surgeon from each program within each hospital would lead to OPO advisory boards with an overwhelming number of members. Therefore, we believe it is advisable to change the language to clarify that even if a hospital has multiple transplant programs, the OPO need have only one transplant surgeon per transplant hospital or hospital system.

In addition, we propose requiring that the transplant surgeon who serves on the OPO board must have practicing privileges and perform transplants in the hospital he or she represents. This requirement would ensure the surgeon has a thorough knowledge of the needs of the transplant hospital and can represent the hospital or hospital system adequately.

When selecting transplant surgeons for their advisory boards, OPOs should strive for representation of all organ types. That is, if an OPO's service area includes heart, liver, lung, pancreas, and kidney transplant programs, the OPO should include a surgeon who performs each type of transplant.

We are proposing to require that OPOs have a governing body (for example, a board of directors) that has full legal authority and responsibility for the management and provision of all services. We believe it is important for efficient operation of an OPO for authority to reside in a single body. The governing body would be responsible for developing and overseeing implementation of policies and procedures necessary for effective administration of the OPO, including fiscal operations, a QAPI program, and services furnished under contract or arrangement, including agreements for these services. We would require an OPO to have a procedure to address potential conflicts of interest for the governing body. In addition, we would require the governing body to appoint an individual to be responsible for day-to-day operation of the OPO. We are requesting public comment regarding the proposed requirement for a governing body, specifically, whether it would be appropriate for the legal authority and responsibility for the management and provision of all OPO services to lie with an individual, rather than a governing body.

We believe the requirements we propose would provide flexibility so that each OPO would be free to choose the most efficient and effective form of administration and governance to suit its own needs and to fulfill its mission of maximizing organ donation.

Condition: Human Resources (Proposed § 486.326)

[If you choose to comment on this section, please include the caption ''Human resources'' at the beginning of your comments.]

The current regulations at § 486.306(e) require an OPO to have ''a director and such other staff, including an organ donation coordinator and an organ procurement specialist, necessary to obtain organs effectively from donors in its service area.'' There are no additional human resources requirements in the current regulations.

We do not believe this single requirement is adequate to ensure that each OPO has a sufficient number of staff members with the proper skills to provide necessary services and to maximize recovery of healthy organs for transplantation. Furthermore, both research studies (which are cited throughout our discussion of proposed § 486.326) and the experiences of our OPO Coordinators provide evidence that having a sufficient number of trained and qualified staff is positively associated with good outcomes, such as increases in organ donation. We also note that one of the best practices identified by the Organ Donation Breakthrough Collaborative is to ''strive to recruit and retain highly motivated and skilled staff.''

Thus, we are proposing human resources requirements that we believe are essential to the functioning of all OPOs. We propose that an OPO would be required to have a sufficient number of qualified staff to ensure that all usable organs are recovered and to provide all required services to the families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.

OPOs would be required to ensure that all individuals who provide or supervise services, including services provided under contract or arrangement, are qualified to perform these duties.

In addition, we would require every OPO to develop and implement a written policy to address potential conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators. In 2002, we cited a Florida OPO whose procurement director owned a company that purchased organs from the OPO and sold them for research—a serious conflict of interest that led to the dismissal of OPO officials. We believe an OPO's conflict-of-interest policy should clearly delineate and prohibit those outside activities or affiliations that have the potential to impact an employee's ability to make impartial decisions that are in the best interests of both the OPO itself and the organ procurement and transplantation system in the United States.

Although the Medicare hospital regulations require hospitals to review credentials and grant clinical privileges to medical staff, it is difficult, if not impossible, for a donor hospital to credential and grant privileges to recovery surgeons and other members of recovery teams who are not members of the hospital's medical staff. Recovery surgeons and other recovery team members may recover organs in a particular donor hospital no more than once in a period of several years. Thus, their work is too limited to undergo effective review by the donor hospital for the granting of clinical privileges.

However, it is imperative that someone ensure recovery personnel are qualified to recover organs in a manner that preserves their viability for transplantation.

Therefore, we propose requiring OPOs to maintain credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO (for example, transplant surgeons from local transplant hospitals who frequently recover organs in the OPO's donor hospitals). In addition, we propose requiring OPOs to ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained. Note that we are not proposing a requirement for an OPO to maintain credentialing records for physicians and other practitioners if they do not routinely recover organs under contract or arrangement with the OPO (for example a transplant surgeon from a hospital outside the OPO's service area). In those circumstances, the OPO would be required only to verify that the transplant surgeon was qualified and trained. This could be accomplished by, for example, contacting the transplant hospital to confirm that the surgeon who will be recovering an organ at one of the OPO's hospitals is credentialed and has privileges at the transplant hospital.

Studies provide empirical evidence that sufficient staffing serves to maximize organ donation. For example, in a report on 12 years of experience at LifeGift Organ Donation Center in Texas, the report's authors commented that LifeGift's staff resources were ''critical to its ability to sustain and increase donation.'' They noted that LifeGift in the 7-year period preceding publication of the report had an 80 percent growth in staff and a 61 percent increase in organ donors. (*T. Shafer, C Van Buren, C Andrews; Program Development and Routine Notification in a Large Independent OPO: A 12-year Review, Journal of Transplant Coordination, Vol. 9, No. 1, March, 1999.*)

A recent report on OPO best practices listed ''timely, on-site response to potential donor referrals'' as a key attribute of a successful OPO. (Preliminary results of a best practices study presented at tri-annual meeting of the South-Eastern Organ Procurement Foundation on September 14, 2000 by R. Randal Bollinger, MD, Ph.D. Chief of the Division of General Surgery, Duke University Medical Center. In addition to Dr. Bollinger, other study authors include Dennis Heinrichs, MBA, President, LifeLink Foundation; and United Network for Organ Sharing (UNOS) staff members.) (Note that UNOS is the organization under contract with the Health Resources and Services Administration to operate the OPTN.)

The report on LifeGift's 12-year experience noted that ''adequate, even 'deep' staffing levels allowed the OPO to respond in person within one hour of referral on every potential organ donor case.'' We do not propose mandating a 1-hour time frame because geographical and other differences in OPO service areas could make such a short time frame impossible to meet. Furthermore, some hospitals contact their OPOs very early in the donation process, which means it may not be necessary for OPO staff to arrive at the hospital within 1 hour. Clearly the ideal time frame is one in which the OPO arrives at the hospital early enough to ensure that all steps in the donation process can take place, and the desired outcome is the recovery of healthy organs.

Therefore, we propose requiring the OPO to provide sufficient coverage, either by its own staff or under contract or arrangement, to screen hospital referral calls for organ donor potential and evaluate potential donors for medical suitability for organ donation in a timely manner. This means that once an OPO receives timely notification from a hospital about a patient who appears likely to be medically suitable for organ donation, the OPO must perform an assessment of the patient's medical suitability for organ donation early enough in the donation process so that there is sufficient time to discuss donation with the family of the potential donor, implement management protocols for the potential donor, place the organs for transplantation, and arrange for recovery and transportation of the organs while they are still viable.

In addition, we propose requiring an OPO to have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of donors, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development. We are not proposing specific staffing levels because we believe each OPO must determine the amount of staff it needs to ensure that families of potential donors are treated with sensitivity and respect and that the maximum number of viable organs are procured and provided to hospitals for transplantation.

However, we can provide guidance to OPOs so that they can determine if the number of staff they have would be ''sufficient'' under the proposed regulation. The determination is based primarily on outcomes, not just the ultimate outcome—procuring a healthy organ for transplantation—but the intermediate steps that lead to the procurement (such as assessing the potential donor and obtaining consent), as well as those critical activities that support and surround the actual donation process (such as hospital development and death record reviews).

An OPO should analyze the flow of the donation process in each of its hospitals, and determine whether the flow is impeded at any point by a lack of staff. Does the OPO have enough staff available at all times to: Assess potential donors promptly; spend as much time as necessary with the family to answer questions and provide support and counseling; manage the potential donor optimally; maximize the number of organs placed for transplantation; and recover (or arrange for the recovery of) organs as quickly as possible?

An OPO should scrutinize its QAPI program and determine whether additional staff would enable the OPO to broaden the scope of its QAPI program and lead to improved performance. Does the OPO have sufficient staff to monitor and evaluate all donation services; recommend steps to improve performance; track performance over time; and perform death record reviews at Medicare and Medicaid hospitals that have a level I or level II trauma center or 150 or more beds (with the exception of psychiatric and rehabilitation hospitals)?

An OPO also should look closely at hospital development staffing because effective hospital development creates a culture that supports and promotes donation. Does the OPO have sufficient staff to make its presence felt in hospitals (particularly those hospitals with high donation potential) by: Developing a relationship with emergency department and intensive care unit staff; providing ongoing education for hospital staff; meeting with hospital leaders and key physicians to gain their support for organ donation; providing donation data and encouraging hospitals to use the data in quality improvement activities?

As stated earlier, we do not propose to establish specific staffing levels because OPOs must have the flexibility to determine their own staffing needs. However, OPOs rightfully will be concerned about how such an imprecise requirement would be enforced. Certainly we understand that for reasons

beyond their control, OPOs (like all other businesses) sometimes will not have enough staff. We would not cite an OPO for having insufficient staff if the insufficiency is temporary or occasional or if the OPO clearly is doing its best to keep staffing at an optimal level. The requirement is intended to give surveyors the option of citing an OPO when there is a pattern of chronic understaffing in critical areas, and the OPO has not taken the appropriate steps to improve the situation (for example, if the board of directors consistently has refused to approve funds for additional staff needed to improve the OPO's performance).

The OPTN/UNOS Council for Organ Availability Requestor Project studied organ donation requestors who have the greatest success in getting families to consent to organ donation. Results of the study suggest that the experience of procurement coordinators is positively associated with increased consent rates; the average ''expert requestor'' has 4 years of experience. The LifeGift report notes that adequate staffing results in a staff that is not ''spread too thin.'' The report also notes that adequate staffing allows, when appropriate, assigning two coordinators to one donor case, which may improve organ yield by allowing one coordinator to focus on donor management while another focuses on organ placement. We believe that adequate staffing by OPOs avoids staff burn out and frequent turnover of organ procurement coordinators, which is a significant problem for many OPOs.

A recent study published in the Journal of the American Medical Association on factors that influence family consent noted, ''Our data strongly indicated that involvement of the family with a professional from the OPO is critical. The time spent with the OPO coordinator was a strong factor associated with the decision to donate.'' (Siminoff, L, Gordon, N, Hewlett, J, Arnold, R. *Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation.* Journal of the American Medical Association. 2001; 286:71–77.) It is clear that adequate staffing can ensure that procurement coordinators have ample time to spend with donor families. (Note that in citing this study, we are not suggesting that hospital designated requestors should not be involved in the donation process. Studies show that involvement of hospital staff with the OPO in requesting consent leads to the highest consent rates.)

Finally, we propose requiring an OPO to provide a sufficient number of recovery personnel, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation. This proposal is based on our OPO Coordinators' knowledge of situations in which organs were not recovered from medically suitable potential because local surgeons or other recovery personnel were not available. Some OPOs prevent these situations by hiring their own recovery personnel. For example, one of the high-performing OPOs studied in the Organ Donation Breakthrough Collaborative, Donor Alliance, has circumvented this problem by hiring ''organ recovery specialists'' with extensive training and experience in organ recovery.

The current OPO regulations have no requirements for an OPO's management of its human resources. We believe that prudent management of human resources, including provision of sufficient education, training, supervision and evaluation, is a fundamental necessity if OPOs are to have expert, highly qualified staff who can maximize organ donation. Ongoing staff training is a necessity at all OPOs in order to maintain staff skill sets and keep up with rapid advances in procurement and transplantation. However, we have found that a few OPOs do not provide these services for their staffs, which leads to confusion about roles and responsibilities, sub-optimal staff functioning, and resultant poor OPO performance. Conversely, our OPO Coordinators have noted lower staff turnover among OPOs that provide education and training and clearly define their staffs' roles and responsibilities.

Therefore, we propose requiring OPOs to provide their staffs with the education, training, and supervision necessary to furnish required services. Training must include, but is not limited to, performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. In addition, OPOs must evaluate the performance of their staff and provide training, as needed, to improve individual and overall staff performance and effectiveness. For example, staff who make donation requests can be evaluated by their consent rates; staff who clinically manage donors can be evaluated by how many organs are recovered and transplanted from donors and whether immediate organ function occurs in the recipient; and hospital development staff can be evaluated by the percentage of cases in which timely donation notifications are made and how often donation requests are conducted collaboratively between OPO and hospital. An OPO can utilize this information to inform the development of training, tailor their training to the needs of their staffs, and identify individual staff who require additional training.

We believe in-depth training for procurement coordinators is particularly critical because procurement coordinators serve on the OPO front lines. They provide counseling to grieving families, explain donation options, make the request for donation, oversee recovery of organs, and package organs for transport to transplant hospitals. One of a procurement coordinator's most critical functions is management of potential donors to maintain the viability of their organs, which is a highly complex and demanding task. Nevertheless, some procurement coordinators have told us their OPOs do not provide sufficient training and supervision for new procurement coordinators, even though inexperienced coordinators run the risk of making errors that can lead to denial of consent or the loss of a donor.

Therefore, in an effort to decrease errors and provide support to the inexperienced coordinator, we are requesting comments on the advisability of including a requirement in the final rule for supervision of an inexperienced procurement coordinator by an experienced procurement coordinator, director of procurement, medical director, or other experienced individual during the consent process and during management of all donor cases. In addition, we are requesting comments on whether experience should be defined by length of service or number of donation cases, what experience thresholds would be appropriate, and how long an inexperienced procurement coordinator would need supervision.

We acknowledge that it can be difficult for OPOs to hire and retain staff with the necessary qualifications, experience, and dedication to fill critical staff positions, particularly procurement coordinator positions, and to provide their staffs with education and training. Many OPOs find high staff turnover to be a significant barrier to increasing organ donation in their service areas. Nevertheless, many OPOs are able to recruit and retain qualified staff by providing training, opportunities for growth, and a supportive atmosphere that encourages independence and innovation. It is clear that the six OPOs whose practices were studied as part of HRSA's Breakthrough Collaborative would all agree that professional, committed, and experienced staff have formed the basis for their success. One of the OPOs, New

England Organ Bank, emphasizes that its devoted staff and low staff turnover are contributing factors to its high performance.

The Collaborative's Best Practices Final Report identified five strategies OPOs can use to recruit and retain skilled and motivated staff.

The first strategy is to use various practices to identify and recruit staff. For example, according to the study report, LifeLink of Florida uses an extensive ''reality'' interview process in which candidates meet with staff and participate in actual organ referral and donation events. This process enables LifeLink to hire staff who are ''aggressive, collaborative, assertive, and able to work under stressful conditions.''

The second strategy is to offer adequate orientation and training. One of the six high-performing OPOs, New England Organ Bank, puts newly-hired staff through a formal training program ''tailored to their specialized function.''

The third strategy is to create a culture of collaboration and autonomy. Every high-performing OPO studied pointed to strong collaborative relationships as a factor that contributes to their success. These OPOs have forged successful relationships both within their own staffs and with outside organizations and other parties in the donation process, such as tissue banks, hospital administrators, physicians, and nurses.

Perhaps the best example of collaboration is the in-house coordinator (IHC) program developed by LifeGift Organ Donation Center in Houston, which places two full-time nurses in all Level I trauma centers. According to the study, the OPO staff are ''fully integrated into hospital operations,'' which promotes ''strong, transparent hospital partnerships.''

The fourth strategy discussed in the study is to offer flexible work environments and other benefits. At Mid-America Transplant Services in St. Louis, OPO staff are given specialized roles in the donation process based on their professional experience. Staff have the flexibility to work from home and are given financial incentives when they meet performance targets.

The fifth strategy noted in the study is to provide opportunities for professional growth and development. The Report's authors provide many examples of the opportunities that the high-performing OPOs provide to their staffs. For example, since most ''family support coordinators'' at Donor alliance have non-clinical backgrounds, the OPO provides extensive training in the medical suitability of organ donors. In another example, Mid-America's two operating rooms are used to give their clinical staff an opportunity to learn new skills and develop professionally.

We urge all OPOs to read the report of the Collaborative, titled, ''The Organ Donation Breakthrough Collaborative: Best Practices Final Report,'' which is available on the Department's Web site at *http://www.organdonor.gov.*

Voluntary OPTN bylaws call for OPOs to have a medical director who is a licensed physician and is responsible for the medical and clinical activities of the OPO. Although current regulations do not require OPOs to have a medical director, most OPOs employ a medical director as part of their management staff and recognize the value and expertise this position brings to their OPO programs. Our OPO Coordinators have found that most high-performing OPOs have active, involved medical directors. Therefore, we propose requiring an OPO to have a medical director who would be responsible for implementation of protocols for donor evaluation and management and organ placement and recovery.

The medical director would be responsible for oversight of the clinical management of donation cases, including providing assistance in the medical management of a donor case when the surgeon on call is unavailable. We would expect that in meeting these requirements, OPOs would have medical directors who oversee clinical donation processes, facilitate best practices, and provide guidance for OPO staff, both clinical and non-clinical, about all clinical donation issues.

We believe the human resources requirements we propose would ensure efficient and effective operation of OPOs, which is in the best interests of the organ donation and transplantation system. In addition, the requirements would further the efficient administration of the Medicare program. As we stated earlier, section 1102 of the Act grants the Secretary the authority to establish requirements necessary for the efficient administration of the Medicare program.

Condition: Reporting of Data (Proposed § 486.328)

[If you choose to comment on this section, please include the caption ''Reporting Data'' at the beginning of your comments.]

The current regulations (§ 486.310) require an OPO to submit data to us annually showing the number of donors, the number of kidneys and extra-renal organs procured, and the number of kidneys and extra-renal organs transplanted so that we can determine whether the OPO has met the performance requirements. We propose broadening this requirement to require OPOs to provide individually-identifiable, hospital-specific organ donation and transplantation data to the OPTN and the Scientific Registry of Transplant Recipients (SRTR), as directed by the Secretary. (Note that at present the SRTR does not collect data; its current mandate is to analyze data collected by the OPTN.) We also propose requiring OPOs to provide hospital-specific organ donation data to transplant hospitals, annually. Finally, we propose requiring OPOs to report individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Department, as requested by the Secretary.

Data could include, but would not be limited to, (1) The number of hospital deaths; (2) results of death record reviews; (3) number and timeliness of referral calls from hospitals; (4) potential donor denominator (as defined in § 486.302); (5) data related to non-recovery of organs, (6) data about consents for donation; (7) number of donors; (8) number of organs recovered (by type of organ); and (9) number of organs transplanted (by type of organ).

We would note that OPOs are specifically exempted from regulatory requirements for the privacy of individually identifiable health care information under the Health Insurance Portability and Accountability Act. Regulations at 45 CFR 164.512(h) state, ''A covered entity may use or disclose protected health care information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye, or tissue donation and transplantation.''

Our reasons for proposing this requirement are three-fold. First, it would bring data reporting requirements for OPOs into agreement with those for transplant hospitals. Hospital regulations at 42 CFR 482.45(b)(3) require transplant hospitals to provide organ-transplant-related data as requested by the OPTN, the SRTR, and the OPOs. Transplant hospitals must also provide those data directly to the Department when requested by the Secretary. Ensuring a flow of data between transplant hospitals and OPOs promotes collaboration and can enable transplant hospitals to improve their programs. For example, a transplant hospital can use data from OPOs in its QAPI program, such as data that allow it to compare its transplantation rates

with those of other transplant hospitals in the OPO's service area or data showing how many times and for what reasons the hospital's own transplant programs have turned down organ offers from the OPO.

Second, CMS Regional Office OPO Coordinators need data from OPOs to target areas for improvement both in OPOs and hospitals, and third, the OIG has recommended CMS use hospital-specific data provided by OPOs to monitor the impact of the hospital CoP and improve hospital compliance with the CoP. In short, we believe these data reporting requirements for OPOs are necessary for the efficient administration of the Medicare program and can be required based on the Secretary's authority under section 1102 of the Act.

We would note that most OPO data needed by us or other agencies within the Department can be obtained from the OPTN or the SRTR. In fact 42 CFR 121.11(b)(2) requires OPOs and transplant hospitals to submit information about tranplant candidates, transplant recipients, organ donors, transplant program costs and performance, and ''other information that the Secretary deems appropriate.'' We would not request data from OPOs if the data were readily available from other sources. We are including this provision only to give us and other entities the flexibility to request data from OPOs if data cannot be obtained expeditiously from other sources. The Secretary would use such data and other information for monitoring of hospital compliance with the CoP, monitoring of OPO compliance with the process performance measures and other requirements, and assisting OPOs with their QAPI programs.

We propose including language that defines how OPOs should report data for donors and organs procured and transplanted to ensure that all OPOs are following the same reporting protocol. A uniform process would ensure accurate reporting and will enable us to make a true comparison of the OPOs' performance. We propose including reporting protocols for the following: ''kidneys procured,'' ''kidneys transplanted,'' extra-renal organs procured,'' and ''extra-renal organs transplanted.'' For example, under ''kidneys procured,'' en bloc kidneys are counted as two kidneys procured. Under ''extra-renal organs procured,'' a heart and two lungs recovered from one donor would count as three organs procured.

In August 2000, the Office of the Inspector General (OIG) for the Department of Health and Human Services released a report on the CoP titled, ''Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule.'' The OIG found that OPOs and hospitals had not yet taken full advantage of the CoP. The OIG noted, ''Maximizing organ donation requires coordination and collaboration between hospitals and OPOs. The donation rule, however, is contained in the Medicare conditions of participation for hospitals. While it provides OPOs with significant leverage that they can use to work with hospitals on donation, the rule places the obligation for compliance solely on hospitals; it sets no requirements for OPOs. Effective implementation of the donation rule requires accountability on behalf of both OPOs and hospitals.''

The OIG recommended that to increase OPO accountability, we require OPOs to provide hospital-specific data on referrals and organ recovery. The OIG stated that obtaining data from OPOs would be the most effective and efficient way to monitor the CoP and assess hospital compliance because OPOs already collect the necessary data and have them readily available. The report states, ''We believe that OPOs could reasonably, inexpensively, and easily provide current data on a quarterly basis.''

We agree with the OIG's conclusions. Although all OPOs collect hospital-specific data on referrals and organs recovered, current regulations do not require OPOs to share these data with us, and OPOs have been reluctant to share data with us voluntarily lest they affect their collegial relationships with their hospitals. Therefore, we must rely on surveys performed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and State survey agencies to monitor hospital compliance. However, JCAHO surveys usually are performed only once every 3 years and State Medicare surveys are performed even less frequently. Moreover, requirements for organ, tissue, and eye procurement are only a small part of hospital accreditation and certification surveys, and surveying for those requirements may have a lower priority than surveying for requirements affecting direct patient care. In fact, the OIG noted that some hospitals reported to them that surveyors asked only to see their policies and procedures for organ donation and did not probe further to determine whether the hospital was complying with all requirements in the regulation.

Based on the OIG's recommendations, HRSA, CMS, and the Association for Organ Procurement Organizations (AOPO) determined what data should be reported to the OPTN (and, in turn, reported by the OPTN to HRSA and CMS). As stated earlier in this preamble, in September 2001, OPOs began reporting the following hospital-specific data electronically to the OPTN: (1) The number of referral calls received from hospitals; (2) the number of potential donors; and (3) the number of consents to donation. The OPTN calls for OPOs to report the number of donors and the number of organs recovered at each hospital. In the future, as data needs are identified (for example, the number of deaths in each hospital), the OPTN may begin collecting additional data. We can obtain data from the OPTN through HRSA at any time. OPOs currently report data to the OPTN within 30 days of the end of the month in which a death occurs, and we propose requiring that OPOs continue to report their data within this time frame. However, if an OPO determined through death record reviews or by other means that the data it reported to the OPTN was incorrect, we would require the OPO to report the corrected data to the OPTN within 30 days of the end of the month in which the error was identified.

The OIG report recommended that we require OPOs to make hospital-specific donation performance data publicly available in order to recognize hospitals that do a good job. They pointed out that one OPO in the nation already publishes organ donation data for every hospital in its service area. We agree that the efforts of hospitals that collaborate with their OPOs and support organ donation should be recognized. Publication of those data has the dual effect of recognizing the efforts of good-performing hospitals, while holding hospitals more accountable for organ donation. In addition, as we note elsewhere in this preamble, if OPOs report the same hospital-specific data publicly that they report to the OPTN, the published data would provide an additional opportunity to verify the completeness and accuracy of the OPTN data. Furthermore, publication of hospital-specific organ donation data would be an effective way to promote the exchange of information among OPOs, hospitals, and the public.

Therefore, we propose requiring OPOs to report hospital-specific organ donation data, including organ donor potential and the number of actual organ donors, at least annually to the public. We would suggest that OPOs include these data in their newsletters and their annual reports.

We are interested in other avenues to hold hospitals more accountable for organ donation and for implementing

the CoP. In fact, the AOPO has requested that we ask for public comment regarding specific actions we might consider to address problems some OPOs have encountered in regard to their hospitals. For example, OPOs have complained to us that hospitals sometimes refer a brain dead patient only after the patient has been removed from the ventilator (rendering the patient medically unsuitable for organ donation) and that hospital staff physicians sometimes are reluctant to declare brain death, provide assistance in evaluating potential donors, or provide services for intraoperative donor management.

We believe it is important to point out, however, that in these specific situations (and many others), there is regulatory relief available to OPOs under the hospital and critical access hospital CoPs, which requires hospitals to refer patients whose death is imminent and to cooperate with their OPOs in maintaining potential donors while necessary testing and placement of organs takes place. This means that a hospital could be in violation of the CoP if it did not refer a brain dead patient before removing the patient from the ventilator or if the hospital did not provide the support services necessary to maintain a potential donor.

We are aware that OPOs are reluctant to provide details about violations of the hospital CoP to us because they fear disturbing their relationships with hospitals. One OPO has stated, ''it's not our intention to find fault with anybody. This is a relationship business.'' However, the CoP for organ, tissue, and eye procurement has been in effect since August 1998. We would suggest that if an OPO has not been able to urge a hospital into compliance with the CoP by now, it needs our assistance. We cannot aid hospitals and OPOs in improving their relationships and assure that all hospitals are complying with the CoP unless OPOs are willing to bring problems to our attention. Nevertheless, we are interested in receiving comments regarding other actions we might take to improve hospital compliance with the CoP and hold hospitals more accountable for organ donation.

[If you choose to comment on this issue, please include the caption ''Hospital Accountability'' at the beginning of your comments.]

Condition: Information Management (Proposed § 486.330)

[If you choose to comment on this section, please include the caption ''Information management'' at the beginning of your comments.]

This section incorporates the data maintenance and record keeping requirements now found at § 486.304(c)(8). We believe these requirements should be retained to ensure that a smooth transition of records would occur if an OPO's service area were taken over by another OPO and so that OPOs maintain adequate information about each donor. We propose that, as in current regulations, an OPO would be required to establish and use an information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop and follow procedures to ensure the confidentiality and security of the information.

OPOs have asked for guidance regarding how long records should be kept. We propose requiring OPOs to maintain donor and transplant recipient records for 7 years because the regulations that govern the OPTN at § 121.11(a)(2)(i) require OPOs to retain records for 7 years. We also propose requiring certain additional data that OPOs would be required to keep in their donor records.

Currently, OPOs are required to include the following in their donor records: information identifying the donor (for example, name, address, date of birth, social security number or other unique identifier, such as Medicare health insurance claim number), organs and (when applicable) tissues recovered, date of the organ recovery, and all test results. We propose requiring the following additional data elements: donor management data, current hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information. We currently require OPOs to keep identifying information for each transplant recipient. We propose requiring OPOs to include a record of the disposition of organs recovered for transplantation.

In proposing these new data elements, we are expanding upon the data elements required for donor records under existing regulations at § 486.304(c)(8). There are three reasons why we propose requiring these additional data elements. First, such data is critically necessary to the investigation of the transmission of infectious disease from organ donors. Recently, CMS and the Centers for Disease Control and Prevention (CDC) needed donor records (including donor management data, hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information) to investigate two separate cases of Hepatitis C transmission from organ donors and to determine whether the donors had been tested, why they had not tested positive for Hepatitis C, and whether the donors had exhibited signs of Hepatitis C that should have been apparent before donation taking place. In addition, CMS and the CDC needed to quickly establish the disposition of all organs recovered from the infected donors to establish whether other organ recipients were infected. Although some of the data we propose requiring would be available from the hospital where a donor died, some would be available from the OPTN, and some would be available from the OPO, it is important for all data to be available in one location to provide speedy access in cases of disease transmission.

In addition, CMS needs access to several of these additional data elements to determine whether an OPO has complied with the process performance measures. Donor management, hospital history, and past medical and social history would be used to assess compliance with § 486.344(a) and (b). Consent and next-of-kin information would be used to assess compliance with § 486.342.

Finally, we believe the additional data elements we propose for donor records would provide an invaluable source of information for OPOs to use in their QAPI programs. For example, an OPO may want to review donors' medical and social histories to assess and improve its protocol for obtaining medical and social histories from potential donor families.

Condition: Requesting Consent (Proposed § 486.342)

[If you choose to comment on this section, please include the caption ''Requesting consent'' at the beginning of your comments.]

In addition to requesting consent for organ donation from families of potential donors, OPOs often request consent for tissue donation on behalf of their hospitals' designated tissue banks. In April 2000, the ''Orange County (CA) Register'' *(Register)* published a five-part series of articles based on its investigation of the tissue banking industry. One of the allegations made by the *Register* was that tissue donor families were not being fully informed before making the decision to donate. The *Register* articles noted that families of potential donors often are not informed about how donated tissues may be used (for example, skin may be used for cosmetic surgery, as well as grafts for burn patients) or that some

tissue banks make profits from donated tissues.

In January 2001, the OIG published a report entitled, ''Informed Consent in Tissue Donation.'' The OIG noted that in recent years, tissue banking and processing practices have gradually diverged from tissue donor families' expectations. The expansion of the tissue banking industry, new technology, large profits, and tissue marketing practices have raised questions about the non-profit basis of tissue banking. Therefore, the OIG suggested that certain steps should be taken in regard to tissue donation to ensure that families and other decision-makers are fully informed before making a decision. One of the OIG's recommendations was that we add a provision to the OPO conditions for coverage to hold OPOs accountable for obtaining informed consent from tissue donor families when OPOs request consent on behalf of tissue banks. The OIG also recommended that we require OPOs to include tissue banks when developing and conducting training for hospital designated requestors for tissue.

We agree with the OIG's recommendations. Providing informed consent is an integral part of encouraging discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families, which is required for hospitals and critical access hospitals under section 1138(a)(1)(A)(ii) of the Social Security Act, in hospital regulations at § 482.45(a)(4), and in critical access hospital regulations at § 485.643, and which we propose as a requirement for OPOs in this proposed rule. Ensuring that all donor families and other individuals responsible for making donation decisions are fully informed before making a decision guards against negative publicity that may result if a donor family does not receive informed consent. As noted earlier in this preamble, negative perceptions of or publicity about tissue donation can affect the public's attitude about organ donation and individuals' willingness to donate. Therefore, we propose requiring that all requests made by OPOs for tissues, as well as organs, include a properly executed informed consent process.

An OPO would be required to have a written protocol to ensure that, in the absence of a donor document, the individual or individuals with responsibility to make the donation decision are informed of their option to donate organs or tissues or to decline to donate. We note that with respect to informed consent, a potential donor may have executed a consent or indicated in an advance directive or power of attorney the individual who will make a decision about organ donation on his or her behalf. The OIG appended to its report a list of model elements of informed consent for organ and tissue donation developed by the American Association of Tissue Banks, AOPO, and the Eye Bank Association of America, as well as an informed consent policy for tissue donation developed by the National Donor Family Council. We have incorporated many of the recommendations made by these organizations into our proposal.

For example, the OIG noted that although tissue donor families assume the tissue they agree to donate will be used to meet important medical needs, tissue is sometimes processed into products used for elective cosmetic procedures. Tissues may also be used for research or education rather than transplantation. To address this issue, the National Donor Family Council recommends that tissue donor families be told they may restrict or limit use of the tissue they donate. We agree with this recommendation and propose requiring that individuals responsible for making the donation decision be informed that they may limit or restrict the use of donated organs or tissues.

In addition, we propose requiring OPOs to provide to the individual(s) responsible for making the donation decision, at a minimum, a list of the organs or tissues that may be recovered; a description of all possible uses for the donated organs or tissues; information (such as non-profit or for-profit status) about organizations that will recover, process, and distribute the tissues; a description of the screening and recovery processes; information regarding access to and release of the donor's medical records; an explanation of the impact the donation process may have on burial arrangements and the appearance of the donor's body; information about the procedure for filing a complaint; contact information in case the individual(s) making the decision have questions; and a copy of the signed consent form.

When developing protocols for informed consent for tissue donation, OPOs may wish to review the informed consent policies appended to the OIG report. The National Donor Family Council represents approximately 8,000 donor families, and the American Association of Tissue Banks accredits 58 tissue banks in the U.S. Their policies include specific descriptions of elements that address full disclosure for consent for tissue donation.

We would note that a recent survey of tissue donor families conducted by the National Donor Family Council and Case Western Reserve University found that a large majority of families said they would have preferred receiving more, rather than less, information to aid them in their decision making. For example, 79 percent of families surveyed said they would have wanted to know that some tissue banks are for-profit entities. To guarantee that all donor families and other individuals responsible for making donation decisions have the information they need to make an informed decision, as well as to avoid a negative impact on organ and tissue donation, we believe information should be provided about all facets of the donation process before a donation decision is made.

Finally, the family of the donor is likely to have many questions about the donation process, even if the OPO does not request consent. Thus, although we do not propose requiring an OPO to seek informed consent if the potential donor consented to donation before his or her death in a manner that satisfied the governing State law requirements, we propose requiring the OPO to provide information about the donation if it is requested by the donor's family.

Condition: Donor Evaluation and Management and Organ Placement and Recovery (Proposed § 486.344)

[If you choose to comment on this section, please include the caption ''Donor evaluation and management, organ placement and recovery'' at the beginning of your comments.]

The current OPO regulations have minimal requirements for donor evaluation and management and organ placement and recovery. They require OPOs only to: (1) Have a system to allocate donated organs equitably among transplant patients consistent with specific CDC guidelines for preventing the transmission of HIV and with the rules of the OPTN; and (2) ensure that appropriate donor screening and infection tests consistent with CDC and OPTN guidelines are performed by a laboratory certified in the appropriate specialty or subspecialty in accordance with CLIA requirements. There are no provisions in our regulations addressing donor management or organ recovery.

We propose requiring every OPO to have written protocols for donor evaluation and management and organ placement and recovery. The OPO would be required to ensure that protocols meet current standards of practice and that established practices and criteria are designed to optimize the number of donors and the number of

organs recovered and transplanted per donor.

As stated earlier, our OPO Coordinators have observed that the most successful OPOs have active, involved medical directors. Therefore, we are proposing requirements to ensure both that every OPO has a medical director and that medical directors are involved in the day-to-day oversight of clinical staff and the staff's evaluation and management of potential donors. We propose that an OPO's medical director would be responsible for ensuring that protocols for evaluation and management of donors are implemented correctly and appropriately to ensure every potential donor is thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

Managing a brain dead potential donor so that organs remain transplantable is very difficult. In fact, experienced OPO procurement coordinators agree that it can be more difficult to manage a brain dead potential donor successfully than to manage a living, critically ill patient. Sometimes donors are lost at this point in the donation process because cardiac arrest occurs before organs can be recovered. Therefore, we propose that OPOs be required to implement a system that ensures the medical director or other qualified physician is available to assist in the medical management of a donor when the surgeon on call is unavailable. We believe these proposals would ensure that once consent is obtained, every medically suitable potential donor will go to surgery and every transplantable organ will be recovered.

We believe detailed protocols whose implementation is well coordinated between the OPO medical director and procurement coordinators would work to safeguard against outcomes that hinder the goal of optimizing recovery of transplantable organs. The complex clinical interventions required for each stage of the donor evaluation and management and organ recovery processes contain numerous variables that would benefit from increased surveillance and accountability.

An excellent example of the importance of following a protocol for donor management can be found in a recent OPTN/UNOS study of the UNOS ''Critical Pathway for the Organ Donor'' protocol for donor management. The study found that when the critical pathway protocol was used, outcomes improved significantly. The number of organs recovered per donor increased by 10.3 percent, and the number of organs transplanted per donor increased by 11.3 percent. (Chabalewski, F., Rosendale, J., Edwards, C.: The Effect of a Critical Care Pathway on Donor Management Time and Cost—A Pilot Study. Presented at the American Association of Critical Care Nurses, May 1, 2000.) The Secretary's Advisory Committee on Transplantation (ACOT) recently recommended that OPOs be encouraged to develop, evaluate, and support the implementation of improved management protocols for potential donors. The ACOT noted that the UNOS ''Critical Pathway'' is a ''novel and improved'' standard of care for heart and lung donors, and the Committee called for development of improved management standards for recovery of other types of organs.

Currently, the CDC's ''Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs'' are appended to our OPO regulations, but we are not proposing to include them in our new regulations. Once guidelines are appended to Federal regulations, agencies can incorporate new guidelines only through the rulemaking process.

Therefore, we propose removing the CDC guidelines from the OPO regulations and requiring, instead, that OPOs arrange for donor screening and testing for infectious disease following current standards of practice. This requirement would give OPOs the flexibility to follow the most up-to-date guidelines for preventing transmission of infectious disease. We would expect OPOs to change their testing practices quickly if the organ donation and transplantation community agrees that a change is indicated.

For example, in 2001 three transplant recipients were infected with the parasite that causes Chagas disease after receiving organs from a donor from Central America. One of the recipients later died from the disease. Chagas disease is endemic in Latin America but had not previously been reported in the United States. Although at present there is no test available in the United States to screen donors or organs for the presence of Chagas disease, if a test becomes available and the OPTN and CDC recommend that OPOs use the test to screen potential donors, we would regard that testing as being part of current standards of practice for donor testing.

We propose requiring that all testing of potential donors (including point-of-care testing and blood typing) be conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 (that is, the CLIA regulations). Thus, an OPO using its own mobile unit to perform point-of-care testing for management of donors before organ recovery would be required to have the appropriate CLIA certification. The OPO would be required to ensure that the donor's blood is typed using two separate blood samples. Furthermore, we would require OPOs to document donor records with all test results, including blood type, before organ recovery.

To provide opportunity for improvements in partnerships between OPOs and the transplant hospitals in their service areas, we would require OPOs to establish protocols collaboratively with transplant hospitals that clearly define the roles and responsibilities of the OPO and the transplant hospital for all activities associated with donor evaluation, donor management, and organ recovery.

In February 2003, a medical error occurred at a large university hospital that made headlines across the country. Surgeons at the hospital transplanted a heart and lungs from a type A donor into a type O recipient. The recipient immediately began to reject the mismatched organs, and a second transplant several days later from a donor of the correct blood type failed to save her life. Although a number of errors and mistaken assumptions on the part of the hospital and both OPOs involved in the procurement of the organs led to the mismatched transplant, it could have been prevented by better communication between the hospital and the OPOs involved in procuring and placing the organ.

Therefore, we propose requiring OPOs to include in the protocol the procedures to be used to ensure that the blood type of the donor is compared with the blood type of the intended recipient by two OPO staff members before organ recovery takes place and that documentation of the donor's blood type accompanies the organ to the transplant hospital.

OPOs would be required to review the protocols periodically with their transplant hospitals to incorporate best practices and maximize placement of transplantable organs. We believe that implementation of current, comprehensive protocols would improve donor evaluation, management and organ recovery and contribute to the maximum number of organs per donor recovered and transplanted.

In our investigation of the mismatched transplant, we found that the OPOs involved did not obtain documentation of the recipient's blood type or position on the waiting list from

the OPTN. Therefore, we propose requiring that before recovery of an organ for transplantation, an OPO must have written documentation from the OPTN showing, at a minimum, the intended recipient's OPTN identification number and blood type, as well as the recipient's position on the waiting list in relation to other suitable candidates. We have included additional safeguards in this proposed rule (see § 486.346) to prevent mismatched transplants.

Section 371(b)(3)(E) of the PHS Act requires OPOs to ''have a system to allocate donated organs among transplant patients according to established medical criteria.'' The OPTN develops the medical criteria upon which allocation policies are based with the input of the organ donation and transplantation community. Therefore, we propose retaining the requirement in the current regulations that OPOs have a system to equitably allocate donated organs among transplant patients consistent with the rules of the OPTN. However, we propose adding language to clarify that the ''rules'' of the OPTN are those that have been approved as enforceable by the Secretary.

We are proposing a requirement that OPOs develop and implement a protocol that maximizes placement of transplantable organs. This means that OPOs should be aware of organ acceptance criteria for centers outside their service areas and make every possible effort to place healthy organs. We would encourage OPOs to include organ placement in their QAPI programs and explore innovative ideas for maximizing both organ recovery and transplantation.

According to the Collaborative's report, LifeLink of Florida evaluates every brain death on-site at the hospital, regardless of the patient's age, medical history, or social history, and makes every effort to find potential recipients for marginal or ''extended criteria'' organs. LifeGift's philosophy includes ''turning potential donors previously considered unsuitable into actual donors.''

Many OPOs have developed innovative methods for maximizing the number of organs they place and recover. For example, the Hawaii OPO has partnered with a California transplant hospital to arrange for hearts donated in Hawaii to be transplanted in California, even though the transport time to California is at the upper limits of the acceptable cold ischemic time for a heart. At the July 2002 meeting of the North American Transplant Coordinators Organization in Washington, DC, OPOs presented case studies and abstracts describing their successes in recovering organs from marginal donors. Gift of Life OPO in Philadelphia presented an abstract documenting its success in implementing a comprehensive initiative for recovering organs from pediatric donors after cardiac death (that is, non-heartbeating donors). From 1995 through 2001, 55 organs recovered by the OPO from pediatric donors after cardiac death were successfully transplanted. Gift of Life also presented an abstract demonstrating the number of viable organs they recovered from donors over the age of 60 and a case study describing how optimal donor management, biopsy, and perfusion enabled them to recover viable kidneys from a donor with initially poor kidney function.

Condition: Organ Preparation and Transport (Proposed § 486.346)

[If you choose to comment on this section, please include the caption ''Organ preparation and transport'' at the beginning of your comments.]

Our current regulations have minimal requirements for OPOs for organ preparation and transport. OPOs are required only to arrange for appropriate tissue typing of organs and to provide or arrange for transportation of organs to transplant hospitals. There are no requirements for organ packaging in the current regulations.

We propose requiring OPOs to arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO would be required to ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

We propose requiring OPOs to develop and follow a protocol for packaging, labeling, handling and transporting organs in a manner that ensures their arrival without compromise to the quality of the organ or the health of the recipient. OPOs would be required to include procedures to check the accuracy and integrity of labels, packaging, and contents before transport, including two separate verifications of the data on the labels and in the documentation that accompanies an organ to a transplant center.

The impetus for this proposal came from an incident that occurred in Illinois in 2000. In packaging organs for shipment, an OPO mixed up the label identifying a kidney intended for transplantation with the label for a heart intended for research. It was only after the intended kidney recipient had been anesthetized and surgery had begun that hospital staff discovered the OPO had sent a heart instead of a kidney.

In investigating the incident, we discovered that while organ mix-ups are rare, they are not unheard of, and no one in the OPO community seemed surprised that it had happened. In fact, the OPTN/UNOS OPO Committee recently documented 15 instances of organ packaging errors that occurred over a period of only 6 months. These errors included three organs shipped without sufficient ice, a right kidney shipped instead of the left kidney expected by the transplant hospital, a vessel container leaking (thus compromising the sterile integrity of segments of the donor's aorta and inferior vena cava intended for use in the transplant procedure), as well as other errors that may have resulted in organ wastage. Although the OPTN has packaging requirements for OPOs, clearly, the requirements have not been sufficient to prevent errors that waste organs and endanger recipients. In light of the critical nature of the organ shortage, such errors are unacceptable.

Finally, an OPO would be required to mark all packaging in which organs are transported with the identification number, specific contents, and donor's blood type. This requirement is one of our proposals to guard against transplantation of organs mismatched by blood type or delivery of the wrong organ to a transplant center.

Condition: Quality Assessment and Performance Improvement (QAPI) § 486.348

[If you choose to comment on this section, please include the caption ''Quality Assessment and Performance Improvement'' at the beginning of your comments.]

There is no requirement in current regulations that OPOs have a QAPI program. Although our regulations for most Medicare providers and suppliers require, at the least, a quality assurance program (the ''find a problem, fix it'' approach), there is no corresponding requirement in the OPO regulations.

QAPI is the process of using objective data to study and continually make improvements to all aspects of an organization's operations and services. QAPI rests on the assumption that an organization's own quality management system is the key to improved performance. It seeks to increase the amount and quality of information on which to base decisions and improve quality. QAPI programs allow health care entities to assess their functioning

continuously and make changes to improve their quality and efficiency.

QAPI is regarded by the health care community as the most efficient and effective method for improving the quality and performance of health care providers. QAPI has become so pervasive that in a recent publication of the Institute of Medicine (IOM) of the National Academy of Sciences, ''Crossing the Quality Chasm: A New Health System for the 21st Century,'' the IOM recommended that the Department itself should monitor and track quality improvements in six key areas including safety, effectiveness, responsiveness to patients, timeliness, efficiency, and equity.

However, as the focus on improving outcomes in health care shifted from quality assurance to QAPI, OPOs seemed to be left behind, perhaps because they do not provide hands-on health care to patients. Nevertheless, an OPO's success in recovering healthy organs impacts patients who need transplants due to end-stage organ failure just as surely as if the OPO were providing direct care to those patients.

Although some OPOs have strong QAPI programs and use them to effect change both within their own organizations and within their hospitals, some OPOs' QAPI programs are inadequate to drive badly needed systemic changes. Some OPOs admit that, as a group, they tend to be reactive rather than proactive, fixing individual problems instead of systems.

Nonetheless, it appears that OPOs are catching up with the rest of the health care community. We know that most OPOs have a quality improvement program. Some programs are comprehensive, highly structured, and completely integrated into the day-to-day operations of the OPO. OPOs with these programs utilize them for data-based decision making and strategic planning. Other OPOs are still developing and formalizing their QAPI programs.

In November 2001, AOPO conducted a survey to assess quality improvement programs among OPOs. Of the 35 OPOs that responded to the survey, approximately 40 percent had been developing a quality program for 2 years or less, and only 43 percent had designated an individual whose primary responsibility was coordinating and monitoring a quality improvement program. However, approximately 67 percent had made quality improvement part of their strategic plans and had developed appropriate measures or indicators of work system effectiveness for most major activities.

However, AOPO notes that due to several factors, there has been significant growth in quality improvement among OPOs since the November 2001 survey. These factors include: (1) The Department's Breakthrough Collaborative, which utilizes QAPI-type strategies to improve donation rates; (2) the Department's initiative to provide comparative data from the SRTR to all OPOs and the public; (3) new perspectives on quality improvement gleaned from individuals hired by OPOs from outside the OPO community; (4) sharing of quality improvement plans among OPOs; and (5) the growth and activism of AOPO's Quality Council. These factors have provided all OPOs with opportunities to expand and improve their quality improvement programs.

All six high-performing OPOs studied during the Organ Donation Breakthrough Collaborative have a process (such as death record reviews) for collecting hospital-specific data and using the data both in their hospital development programs and to effect change within their own organizations. New England Organ Bank collects and monitors hospital-specific data on requests, consents, organs recovered, and organs transplants and reviews the data with hospital leadership every month. Included in their QAPI program are ''formalized feedback mechanisms,'' such as weekly meetings with OPO staff, monthly meetings with hospital staff, post-donation briefings with all involved OPO and hospital staff, along with two data reporting mechanisms (quantitative and qualitative reports).

We believe it is critical for every OPO to have such a comprehensive QAPI program (that is, a program that addresses all aspects of an OPO's functioning and the functioning of its hospitals in the organ donation process). As a recent article describing characteristics of successful OPOs pointed out, ''OPOs no longer have the luxury of using trial and error in determining which programs will increase organ donation, which factors are key for success.'' (Shafer, T., Kappel, D., Heinrichs, D., Strategies for success among OPOs: a study of three organ procurement organizations. *Journal of Transplant Coordination.* V.7, No.1: 22–31.)

Therefore, we are proposing a requirement for every OPO to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate all donation services, including services provided under contract or arrangement. The OPO's QAPI program must include the use of objective measures to evaluate and demonstrate improved performance with regard to OPO activities.

These requirements are based on our commitment to encouraging continuous quality improvement for all Medicare providers and suppliers. As we develop new regulations, we are shifting our focus from targeting the substandard practices of a small number of poor performers to emphasizing the responsibility of all Medicare providers and suppliers for continuous quality improvement in their own organizations. QAPI is a regulatory requirement for hospitals, Medicare + Choice providers, and providers in the Program for All-Inclusive Care for the Elderly (PACE). QAPI has been proposed as a requirement for home health agencies and rural health clinics. We believe a requirement for OPOs to have a QAPI program will encourage continuous quality improvement, as well as the use of best practices, as determined by the individual OPO and the OPO community.

We do not intend to stipulate specific activities an OPO must include in its QAPI program. However, we suggest that all OPOs track and take actions to improve their consent rates. Although knowledge is the foundation for performance improvement, some OPOs do not know their consent rates, either for their service area as a whole or for individual hospitals. Nationwide, the consent rate to organ donation hovers around 50 percent, and it is generally agreed that families' failure to consent to donation is the single most important roadblock to increasing donation. Although there is some evidence that public education efforts targeted toward increasing the public's awareness of and support for organ donation may result in an increase in consent rates, the single greatest opportunity for increasing consent rates lies within the interaction among OPO staffs, hospital staffs, and potential donor families.

We propose requiring an OPO's QAPI program to include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of response to hospital referrals, consent practices, organ recovery, and organ packaging and transport. The OPO would be required to take actions that result in performance improvements and track performance to ensure that improvements are sustained.

There are many resources available to OPOs to develop and improve QAPI within their organizations. The AOPO Quality Council is available to assist all

AOPO members interested in QAPI. The Council has a quality improvement list serve and a chat room used for mentoring and for scheduled discussions of quality improvement topics. The Council holds meetings for all interested OPOs three times per year, with training in basic and intermediate level QAPI, basic quality assurance statistics and data analysis, implementation of quality plans, flow charting, root cause analysis, and preparation for audits and surveys.

In addition, the resources of both CMS (through the OPO Coordinators) and HRSA's Division of Transplantation (DOT) are available to OPOs to assist them in implementing QAPI. CMS OPO Coordinators are always available to assist OPOs with their QAPI programs. Once a final rule is published, the CMS OPO Coordinators will provide guidance to OPOs so that they thoroughly understand how to implement the QAPI requirements in the regulation.

When OPOs are surveyed to see if they meet the requirements for QAPI, surveyors initially would focus on whether an OPO has or is developing a QAPI program. If a QAPI program were still in the development phase, surveyors would determine what remains to be accomplished, what steps the OPO needed to take to have a comprehensive, fully integrated program, and what resources it would need to reach that goal. When an OPO is surveyed for the QAPI requirement for the first time under the final OPO rule, the OPO would not be cited for being out of compliance, as long as it had a QAPI program in some stage of development and was working to expand and improve the program with the goal being a comprehensive, data-driven program to monitor and evaluate all donation services.

The hospital CoP at § 482.45(a)(5) and critical access hospital CoP at § 485.643 require hospitals to cooperate with OPOs in reviewing death records to improve identification of potential donors. We included this requirement in the hospital and critical access hospital CoPs because missed opportunities for donation are not uncommon, and review of hospitals' death records is essential for both OPOs and the hospitals they serve to determine where and how systems need to be changed to ensure future potential donors are identified.

We propose requiring hospital death record reviews as a component of every OPO's QAPI program. OPOs would be expected to use data from their death record reviews as the basis for their quality improvement efforts. We believe that to have sufficient data on which to base changes in their organizations, OPOs must perform death record reviews on an ongoing basis. Death record reviews provide information about nearly the entire range of an OPO's critical operations, as well as the performance of the OPO's hospitals in the donation process. Death record reviews provide information about the timeliness of hospital referrals of potential donors, the timeliness of the OPO's response, OPO or hospital staffs' interactions with family members, management of potential donors, and other matters that affect quality. The information OPOs gain from periodic death record reviews can be used to identify and correct systemic problems that interfere with organ donation.

In a 1997 article, ''Medical Record Review as a Measure of the Effectiveness of Organ Procurement Practices in the Hospital,'' [*The Joint Commission Journal on Quality Improvement*, Vol. 23, No. 6, June 1997] The Partnership for Organ Donation concluded that death record reviews provide a solid foundation for identifying gaps in organ procurement performance, implementing and tracking the success of [quality improvement] initiatives, and monitoring ongoing performance The researchers recommended that OPOs conduct death record reviews annually at large hospitals where medically suitable donor candidates are concentrated and provide feedback from the death record reviews to key hospital staff concerning practice improvements that could be adopted. The researchers suggested annual death record reviews at hospitals with 150 or more beds or with trauma centers.

As stated earlier, the organ donation community recognizes that death record reviews are the ''gold standard'' for assessing donor potential and improving organ donation rates. In fact, in discussions with directors of OPOs that perform death record reviews, we were told that OPOs that do not perform them are ''missing the boat'' because they have no way of knowing their true donor potential and no way of identifying and addressing problems. Although death record reviews are labor intensive, they are well worth the effort expended.

The Michigan OPO, Gift of Life, recently demonstrated what can be accomplished by using death record reviews as the basis for improving organ donation rates. The OPO used data from death record reviews performed monthly in Michigan's leading organ donation hospital to determine that organ donors could be increased in key critical care units in the hospital. The OPO partnered with the hospital to increase organ donation rates. The OPO made a commitment to (1) Respond on site to every referral; (2) provide monthly in-service education to resident physicians in the key units; and (3) follow up on all cases within 96 hours of every referral to obtain information for improving systems for donation. The result—from 2000 to 2001, the hospital's organ donation rate increased by 48 percent to 40 donors and the rate of organs recovered increased by 43 percent to 143 organs.

At the Joint American Transplant Meeting, ''Transplantation 2001'' conference held from May 11–16 2001 in Chicago, a group of researchers, including the researchers from the AOPO death record review study, presented results from a study that used death record reviews to understand opportunities for increasing organ donation within an OPO service area. The researchers concluded that: (1) Increasing organ donation can be achieved by focusing on hospitals with 150 or more beds known to have organ donor potential by death record review; (2) death record reviews offer an objective way to prioritize hospitals by potential and to tailor interventions within each hospital to address specific obstacles to donation; and (3) by focusing on hospitals with 150 or more beds, OPOs can reach more than 90 percent of their target market.

Therefore, we propose that an OPO be required to conduct death record reviews in every Medicare or Medicaid participating hospital with which it has an agreement if the hospital has 150 or more beds or if it has a level I or level II trauma center, with the exception of psychiatric or rehabilitation hospitals. (We propose excluding psychiatric and rehabilitation hospitals because of their limited organ donation potential.) When missed opportunities for donation are identified, the OPO would be required to implement actions to improve performance.

As part of the QAPI process, an OPO would be required to investigate adverse events and complete a thorough analysis. An adverse event for an OPO could be caused by mismanagement of a donor, failure to test organs for infectious disease, failure to compare the blood type of the donor with the blood type of the intended recipient, or mixing up the labels on packaged organs. Examples of situations involving direct patient outcomes that might qualify as adverse events include but are not limited to: (1) Avoidable loss of a medically suitable potential donor for whom consent for donation has been

obtained; (2) avoidable loss of a viable organ; (3) transmission of infectious disease to a recipient, and delivery to a transplant center of the wrong organ (for example, a left kidney instead of a right kidney or a kidney instead of pancreas) or an organ whose blood type does not match the blood type of the intended recipient.

In addition, we are proposing that an OPO be required to report an adverse event to us within 10 business days of becoming aware of the event and provide written documentation of the investigation and analysis of the adverse event to us within 15 days of becoming aware of the event. The OPO would be required to implement changes and safeguards to decrease the probability of the adverse event recurring. We believe that this formal analysis is essential to examining an OPO's existing policies and practices, improving the organ donation process, and improving outcomes. We believe the proposed time frames for reporting and providing written documentation would be sufficient and would ensure prompt attention by the OPO to adverse events.

We believe the requirements we propose for OPOs to develop and implement QAPI programs, perform death record reviews, report and analyze adverse events, and operate under a CAP, as needed, would provide concrete steps OPOs can use to improve their operations and increase organ donation. We also believe these proposed requirements are the single most important provision in this proposed rule to fulfill the congressional mandate for process performance measures based on empirical evidence of organ donor potential and other related factors in OPO service areas.

Additional Conforming Changes (§ 413.200, (§ 413.202, § 441.13, and § 498.2)

In addition to the changes discussed above, we are also proposing a number of conforming and correcting amendments.

As discussed previously, we propose making changes to § 498.1 to remove OPOs from the definition of ''supplier'' under part 498. Since we propose a process for OPOs to appeal a de-certification on substantive and procedural grounds, OPOs would not need the part 498 appeals process.

We also propose to correct a number of cross-references related to the certification of OPOs. In § 441.13(c), and in § 498.2, we propose to change references to ''part 485, subpart D'' to read, ''part 486, subpart G''. On September 29, 1995 (60 FR 50447), the conditions for coverage for OPOs was re-designated from part 485, subpart D to part 486, subpart G. When this re-designation occurred, these two references were not amended to reflect the change.

In addition, § 413.202 refers to OPOs ''as defined in § 435.302 or this chapter''. This is an error. We propose correcting this reference to read ''as defined in § 486.302 of this chapter''.

Request for Comments on Related Issues

Living Donation

[If you choose to comment on this section, please include the caption ''OPO role in living donation'' at the beginning of your comments.]

In 2001, living donors outnumbered deceased donors for the first time, with 6,445 living donors and only 6,077 deceased donors. However, with the exception of two pilot programs in which OPOs assist transplant hospitals by arranging for medical and psychological evaluations of voluntary living kidney donors, the 59 OPOs do not play a role in living donation; their mission is to increase the number of deceased donors. Given the demonstrated risks to donors (primarily living liver donors), we believe that living donation should remain a medical decision between individuals interested in donating and their physicians. However, in view of the increasing importance of living donation, we are specifically requesting public comments on what role, if any, OPOs should play in living donation.

Public Education

[If you choose to comment on this section, please include the caption ''Public Education'' at the beginning of your comments.]

The current regulations at § 486.306(p) require that OPOs conduct and participate in professional education concerning organ procurement, but they do not contain a requirement for public education. However, most OPOs are aware of the importance of the role public education plays in reaching ethnic populations, dispelling myths about organ donation, and addressing other issues that create barriers for consent to donation. Many in the OPO community believe that targeted public education about organ donation plays a key role in overcoming these barriers. Some researchers however, believe that available funding should go to basic research, professional education, and hospital development rather than public education.

While we believe that systematic efforts by OPOs to identify specific barriers to donation, along with public education programs designed to address those barriers, may result in increased rates of consent to donation among targeted populations, the OPO community appears to lack consensus about this issue. Therefore, we have not included requirements for public education in this proposed rule. However, we are specifically requesting comments on the advisability of requiring OPOs to conduct public education based on systematic evaluation of specific barriers to donation within their individual service areas.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

General Requirements (§ 486.304)

For designation purposes, an organization would have to meet specified requirements, including:

It would have to have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for organs provided to transplant centers.

It would have to submit to CMS a written application for designation, using the application form prescribed by CMS.

It would have to document that it has a defined service area that meets the requirements of § 486.306.

An OPO would have to enter into an agreement with CMS. In the agreement,

the OPO would have to agree to do comply with the following ICRs:

(1) Maintain compliance with cited laws, regulations and rules of the OPTN, as defined by § 486.20, and to report promptly to the Secretary any failure to do so.

(2) File a cost report in accordance with § 413.24(f) of this chapter within 5 months after the end of each fiscal year.

(3) Provide budget or cost projection information as may be required to establish an initial interim payment rate.

The ICRs in this section are those that would require an OPO to have accounting and other fiscal procedures; to submit a written application for designation, using a form prescribed by CMS; to enter into an agreement with CMS; and to document that it has a defined service area that meets specified requirements.

These ICRs are currently approved under OMB approval #0938–0512.

OPO Service Area Size Designation and Documentation Requirements (§ 486.306)

Under this section, an OPO would have to make available to CMS documentation verifying that the OPO meets the requirements of paragraph (b) and (c) of this section at the time of application and throughout the period of its designation.

Under paragraph (c), Service area location and characteristics, an OPO would have to precisely define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area for which U.S. population statistics are available.

(3) Total population in service area.

(4) The number of and the names of hospitals in the service area with an operating room and the equipment and personnel to retrieve organs.

The ICR in this section would be that requiring making documentation available. We believe that it would take a typical OPO an average of 1 hour to make the information available. There are 59 OPOs that would have to comply with this requirement; therefore, there would be a total of 59 hours needed to comply annually.

Designation of One OPO for Each Service Area (§ 486.308)

If CMS changes the OPO designated for an area, hospitals located in that area would have to enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

A hospital would be able to request and CMS might grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital would have to submit data to CMS establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

The burden associated with this section is the time it would take a hospital to request a waiver and to create an agreement with an OPO. We estimate that there will be 6 hospitals that would request a waiver and that all of these would need to enter into an agreement with the designated OPO.

Under 5 CFR 1320.3(c), a ''collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the ICRs of this section are not subject to the PRA.

Changes in Ownership or Service Area (§ 486.310)

Under this section, a designated OPO considering a change in ownership or in its service area would have to notify CMS before putting it into effect and would have to obtain prior CMS approval. In the case of a service area change that results from a change of ownership due to merger or consolidation, the entities would have to submit anew the information required in an application for designation. The OPO would have to provide information specific to the board structure of the new organization, as well as operating budgets, financial information, or other written documentation CMS determines to be necessary for designation.

The burden associated with this section is the time it takes to gather and submit the information CMS needs. We estimate that two OPOs would be affected annually and that it will be the same amount of time it would take a potential OPO requesting designation and is covered under OMB approval #0938–0512.

De-Certification (§ 486.312)

Under this section, if an OPO wishes to terminate its agreement, it would have to send written notice of its intention with the proposed effective date to CMS. In the case of voluntary termination, the OPO would have to give prompt public notice of the date of termination, and such information regarding the effect of that termination as CMS may require, through publication in local newspapers in the service area. In the case of involuntary termination, CMS gives notice of the date of termination.

The burden associated with these requirements is the time it would take to send written notice to CMS and to publish pertinent information in the local newspapers. We estimate that one OPO would be affected by these requirements per year.

Under 5 CFR 1320.3(c), a ''collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the ICRs of this section are not subject to the PRA.

Appeals (§ 486.314)

Under this section, if an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive or procedural grounds. The OPO must file its appeal within 30 calendar days of the date of the notice of de-certification. In its appeal, the OPO may submit evidence to demonstrate why it should not be de-certified.

The burden associated with this provision is the time it will take an OPO to file an appeal. We do not expect to decertify more than three OPOs in a given year.

Under 5 CFR 1320.3(c), a ''collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the ICRs of this section are not subject to the PRA.

Re-Certification and Competition Processes (§ 486.316)

Under this section, OPOs competing for the open service area must submit an acceptable plan to increase organ donation in the open service area. An acceptable plan to increase organ donation would, at a minimum:

(1) Be based on the competing OPO's experience and success in its own service area;

(2) Include an analysis of existing barriers, both internal and external, to increasing organ donation in the open area; and

(3) Provide a detailed description of specific activities and interventions for increasing organ donation in the open area.

The burden associated with this requirement is the time it would take to create the plan and to submit it. We expect that it would take approximately 16 hours to develop an acceptable plan to increase organ donation. In each of the 1996, 1998, and 2000 re-certification cycles, approximately two to three OPOs failed the performance standards. Therefore, we do not anticipate terminating more than three OPOs in any four-year period. In previous re-certification cycles no more than two OPOs have competed for an open service area. Therefore, we do not believe that more than two OPOs would compete for an open area. Therefore, we expect that no more than 6 OPOs would compete for service areas of OPOs being de-certified by CMS.

We propose limiting competition for the service areas of OPOs that have met the conditions of coverage to OPOs that have met 4 out of 5 outcome measures at 100 percent of the mean and whose conversion rate of potential donors to actual donors is at least 15 percentage points higher than the incumbent's conversion rate. It is likely that no more than 15 OPOs (those in the upper quartile) would fall into this category.

Therefore, we expect that no more than 21 OPOs would want to develop an acceptable plan to increase organ donation as part of a bid to expand into a new service area. Assuming that it would take 16 hours to develop such a plan, the burden would be 336 hours.

Condition: Relationships With Hospitals, Tissue Banks, and Eye Banks (§ 486.322)

Under this section, an OPO would have to have a written agreement with 95% of the Medicare and Medicaid hospitals in its service area that have both a ventilator and an operating room, that describes the responsibilities of both the OPO and hospital in regard to the requirements for hospitals in § 482.45. The agreement would have to address the requirement in § 486.326 that the OPO would have to maintain credentialing records for physicians who routinely recover organs in hospitals under contract or arrangement with the OPO and would have to assure that physicians and other practitioners who recover organs in hospitals are qualified and trained.

The burden associated with these ICRs would be the time it will take an OPO to enter into an agreement with a hospital. Currently, OPOs are likely to have agreements with all hospitals in their service areas because the hospital CoP for organ, tissue, and eye procurement, which was effective August 21, 1998 (see section 482.45) requires all hospitals to have agreements with their OPO. We believe that it would take an average of two hours to draft an agreement with a hospital.

Condition: Administration and Governing Body (§ 486.324)

Under this section, the OPO would have to have bylaws for its board(s) that address conflicts of interest, length of terms, and criteria for selecting and removing members.

A governing body or individual would have to have full legal authority and responsibility for the management and provision of all OPO services and would have to develop and implement policies and procedures necessary for the effective administration of the OPO, including services furnished under contract or arrangement, fiscal operations, and continuous quality assessment and performance improvement.

The OPO would have to have a procedure to address conflicts of interest for the governing body or individual described above.

The burden associated with the above requirements is the time it would take an OPO to create bylaws and to develop policies and procedures necessary for the effective administration of the OPO. It is usual and customary business practice to have such bylaws, policies, and procedures; therefore, there would be no additional burden.

Condition: Human Resources (§ 486.326)

The first ICR in this section is that we would require the OPO to have a written policy that addresses conflicts of interest for the OPO's director, medical director, and senior management, and procurement coordinators.

Another ICR would be that the OPO must maintain credentialing records for physicians who routinely recover organs in hospitals with which the OPO has an agreement.

The third ICR is that the OPO would have to reevaluate staff competency at least yearly and provide individual job descriptions and performance expectations to staff.

The burden associated with this section is the time it would take an OPO to document policy, maintain records and to provide job descriptions and expectations. These requirements reflect usual and customary business practices and thus do not create any additional burden.

Condition: Reporting of Data (§ 486.328)

Under this section, the OPO would have to provide individually identifiable, hospital-specific organ donation and transplantation data to the OPTN and the SRTR, as directed by the Secretary. The OPO would have to provide hospital-specific data directly to transplant hospitals, annually. In addition, the OPO would be required to provide individually identifiable, hospital-specific organ donation and transplantation and other information to the Secretary, as requested. Such data may include, but are not limited to—

(1) Number of hospital deaths;

(2) Results of death record reviews;

(3) Number and timeliness of referral calls from hospitals;

(4) Potential donor denominator (as defined in 486.302);

(5) Data related to non-recovery of organs,

(6) Data about consents for donation;

(7) Number of donors;

(8) Number of organs recovered (by type of organ); and

(9) Number of organs transplanted (by type of organ).

This section would also require that potential donor data reported to the OPTN to be used for OPO re-certification would have to include data for all deaths that occurred in hospitals in the OPO's service area, unless a hospital has a waiver to work with a different OPO. If an OPO determines through death record review or other means that the potential donor denominator data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN.

The OPO would have to report hospital-specific organ donation data to the public at least annually.

The burden associated with these requirements is the time it would take the OPOs to report certain information. We believe that this would take no more than 4 hours per OPO per year, or a national total of 236 hours. In addition, although it appears this requirement has the potential to add a significant new reporting burden, OPOs are required as a condition of their membership in the OPTN to report a large amount of data to the OPTN (which, in turn, provides the data to the SRTR for analysis). For example, the cadaver donor registration form (OMB approval #0915–0157) OPOs are required to complete for each donor contains more than 300 data elements. In addition, 42 CFR 121.11(b)(2) requires OPOs and transplant hospitals to submit information about transplant candidates, transplant recipients, organ donors, transplant program costs and performance, and ''other information that the Secretary deems appropriate.'' Thus, most information needed by the OPTN, the SRTR or the Department is already being reported by OPOs.

We cannot quantify the number of hours it would take to comply with the data reporting requirement, as data would be requested on an as-needed basis. We believe that almost any OPO data needed by CMS or other agencies within the Department could be obtained from the OPTN or the SRTR. We are including this provision only to give CMS and other agencies the flexibility to request data from OPOs in the event that needed data cannot be obtained expeditiously from the OPTN or the SRTR. We would not request data from OPOs if the data were readily available from other sources.

Concerning the requirement that OPOs give data to the public, almost all OPOs publish newsletters to inform the public of their activities, and, most likely, OPOs would report the hospital data in their newsletters at very little additional cost. For those OPOs that do not publish newsletters, we estimate that it would take 4 hours to create a document suitable for publication yearly. We estimate that three OPOs do not have newsletters, for an annual burden of 12 hours.

Condition: Information Management (§ 486.330)

The ICRs under this section would require the OPO to maintain a record for every donor. The record would have to include, at a minimum, information identifying the donor (for example, name, address, date of birth, social security number), organs and (when applicable) tissues and eyes recovered, date of the organ recovery, donor management data, all test results, current hospital history, past medical and social history, pronouncement of depth, consent and next-of-kin information. Donor records would have to be maintained in a human readable and reproducible format for 5 years.

The OPO would have to maintain data in a format that can readily be continued by a successor OPO and would have to provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement would include records of individual donors, records on transplant candidates (including identifying data and data on immune system and other medical indications) and procedural manuals and other materials used in conducting OPO operations.

Although these ICRs would be subject to the PRA, we believe that all of them reflect usual and customary business practice and therefore have no added burden.

Condition: Informed Consent (§ 486.342)

The ICRs of this section would require that an OPO have a written protocol to ensure that the individual(s) making the donation decision for each potential organ donor is informed of their options to donate organs and tissues or eyes (when the OPO is making a request for tissues or eyes) or to decline to donate and are given sufficient time to consider their decisions and sufficient information on which to base fully informed decisions. The OPO would have to provide to the individual(s) making the donation decision, at a minimum, the following:

(1) A list of the organs, tissues, or eyes to be recovered,

(2) All possible uses for the donated organs and/or tissues,

(3) The information that the individual(s) have the right to limit or restrict use of the organs or tissues,

(4) A description of the screening and recovery processes,

(5) Information (such as profit or non-profit status) about organizations that will recover, process, and distribute tissue,

(6) Information regarding access to and release of the donor's medical records,

(7) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body,

(8) Information about the procedure for filing a complaint,

(9) Contact information in case the individual(s) have questions, and

(10) A copy of the signed consent form.

If an OPO does not request consent to donation because a potential donor consented to donation prior to his or her death in a manner that satisfied applicable State law requirements, the OPO must provide information about the donation to the family of the potential donor, as requested.

We believe that all OPOs currently have policies regarding informed consent, so there would basically be no additional burden to them as the policies are usual and customary business practice. (Some OPOs might have to add some information, which could minimally increase the time it takes to inform the individual(s) making the donation decision.)

Condition: Donor Evaluation and Maintenance and Organ Placement and Recovery (§ 486.344)

Under this section, the OPO must have an effective written protocol for donor evaluation and management and organ placement and recovery.

The OPO must document the donor's record with all test results, including blood type, prior to organ recovery.

Prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended recipient's position on the waiting list in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

The burden associated with this requirement is the time it would take to create the protocols. We believe that good business practices would dictate that an OPO have written protocols that meet the requirements of this section. Therefore, there would be no additional burden.

Condition: Organ Preparation and Transport (§ 486.346)

The ICR in this section requires that the OPO develop and follow a written protocol for packaging, labeling, handling and shipping of organs in a manner that ensures their arrival without compromise to the quality of the organ or health of the recipient. The protocol would have to include procedures to check the accuracy and integrity of labels prior to transport.

The burden associated with this requirement is the time it would take to create the protocols. We believe that good business practices would dictate that an OPO have written protocols that meet the requirements of this section. Therefore, there would be no additional burden.

Section 486.348 Condition: Quality Assessment and Performance Improvement (QAPI)

The ICRs under this section would require the OPO to develop, implement, and maintain a comprehensive, data-driven quality assessment and performance improvement (QAPI) program designed to monitor and evaluate ongoing and overall performance of all donation services, including services provided under contract or arrangement

An OPO would have to establish in writing a policy to address adverse events that occur during any phase of an organ donation case. The policy would have to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events.

The OPO would have to report an adverse event to CMS and would have to provide to CMS written documentation of the investigation and analysis of the adverse event within 15 days of reporting the adverse event.

The burden associated with these requirements would be the time required to develop a QAPI and policy regarding adverse events. It is also the time it would take to report the adverse events to CMS.

We believe that, as part of its usual and customary business, a typical OPO would already have a QAPI and a policy regarding reviewing adverse events.

While we believe that each of the 58 OPOs already has a QAPI program in place, the burden of reporting adverse events is subject to the PRA. We estimate that on average, CMS would receive 30 adverse event reports annually. We have assumed that each report would require 30 minutes to prepare, yielding a total annual burden of 15 hours.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attn.: Dawn Willinghan, CMS–3064–P, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer.

Comments submitted to OMB may also be e-mailed to the following address: e-mail: *CMartin@omb.eop.gov*; or faxed to OMB at (202) 395–6974.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA)(September 19, 1980 Pub. L. 96–354). Section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This proposed rule is an economically significant rulemaking under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of $6 million to $29 million in any one year. For purposes of the RFA, all OPOs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For the purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of $110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose substantial direct requirement costs on State or local governments and does not preempt State law or have other Federalism implications.

Section 701 of Pub. L. 106–505, which was passed by Congress in 2000, requires us to promulgate regulations with new OPO outcome measures and to certify OPOs under those new measures by January 1, 2002. The new outcome and process performance measures must rely on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each OPO's service area. The regulations must include multiple outcome measures.

All 59 OPOs would be affected by the requirements in this proposed rule to a greater or lesser degree. Many—probably the majority—of OPOs have already put into practice many of the requirements we propose. However, OPO practices vary widely. Some requirements would impact many OPOs but have relatively little economic impact; others would have a larger economic impact but would impact very few OPOs. Thus, while we do not believe the requirements in this proposed rule would have a substantial economic impact on a significant number of OPOs, we believe it is desirable to inform the public of our projections of the likely effects of the final rule on OPOs. It is important to note that since OPOs are paid by the Medicare program on a cost basis, any additional costs that exceed an OPO's annual revenues would be fully reimbursed by the Medicare program.

Our projections are based largely on data and information provided by the CMS OPO Coordinators. Each Coordinator is responsible for the OPOs located in one of the four CMS Consortia areas (Midwest, West, South, and Northeast). In some cases, no data were available for one or more of the Consortia. However, OPO practices typically vary by size and affiliation (hospital-based or independent), rather than by geographic location. Since all types of OPOs are represented within each Consortium, we feel confident that the practices and experiences of the OPOs within two or three of the Consortia are representative of all OPOs. Therefore, where data were not available for all four Consortia, we based our projections on data from fewer than four.

The provisions of this proposed rule would have a very limited economic impact on hospitals. It is expected that improved OPO performance would result from the rule and would increase organ donation and, therefore, the number of organs available for transplantation. However, transplant hospitals are reimbursed for their costs related to performing transplants, and donor hospitals are reimbursed by OPOs for the cost of maintaining potential donors. Therefore, there are no negative economic impacts on hospitals that would result from the rule.

Reason for This Regulation

Approximately 70 people receive an organ transplant every day. However, another 16 die due to the lack of transplantable organs (*http://organdonor.org*). OPOs play a critical role in securing transplantable human organs for seriously ill patients suffering from end-stage organ failure. In fact, OPO performance is one of the most critical elements in the nation's organ transplantation system. An OPO that is effective in procuring organs and delivering them safely to transplant centers clearly will save more lives than an ineffective one.

In passing the Organ Procurement Organization Certification Act of 2000, Pub. L. 106–505, Section 701, Congress made certain findings related to OPOs and the current re-certification process for OPOs. These findings included:

a. Organ Procurement Organizations play an important role in increasing organ donation.

b. The uncertainty that resulted from the Department of Health and Human Services' current certification and recertification process was actually interfering with the OPOs' effectiveness in increasing the level of organ donation.

c. The limitations noted in the DHHS' recertification process included:

i. Sole reliance on population-based measures of performance that do not take into consideration a particular population's organ donation potential.

ii. No allowance for other outcome and process standards that may more precisely reflect each OPO's performance and potential.

iii. Lack of a process to appeal for recertification on either procedural or substantive grounds to the Secretary of DHHS.

The Organ Procurement Organization Certification Act required that the Secretary of DHHS promulgate regulations that incorporate certain key requirements. Those requirements have been incorporated into this proposed rule.

Congress clearly wanted the Secretary to establish a certification process that would decrease the uncertainty inherent in the current CMS certification process and improve OPO performance. The goal was to increase organ donation and the number of transplantable organs available for persons experiencing organ failure. We believe that this proposed rule establishes certification and competition processes that will meet those goals.

1. Feasible Alternatives for Competition Among OPOs for Service Areas

Under this proposed rule, OPOs may compete for an OPO's service if the OPO has been de-certified by CMS. OPOs may also compete for other OPOs' service areas at the end of each 4-year re-certification cycle. OMB Circular A–4 recommends that agencies explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. CMS believes that an important policy decision in this rulemaking is the level of competition that would be allowed between the OPOs.

Three levels of competition were considered. We have defined these alternatives, some of which are also discussed in the preamble, as:

a. Full Competition. Every OPO that has met the re-certification criteria would be eligible to compete for another OPO's service area.

b. Limited Competition. Only those OPOs that meet specific criteria would be allowed to compete for another OPO's service area.

c. Restricted Competition. The only competition allowed between OPOs would be for the service area of an OPO that had been de-certified by CMS.

In this proposed rule, CMS has attempted to strike a balance between the costs of competition in terms of resource use and disruption of normal business operations and the benefits of competition, namely the ability of competition to improve performance and inspire innovative activity.

Under this proposed rule, we would select an OPO to replace an incumbent OPO if, in our assessment, the OPO could significantly increase organ donation within that service area. This assessment would be based on the past performance of the competing OPOs and our assessment of the plans to increase organ donation submitted by each competing OPO. These plans would, at a minimum:

a. Be based on the competing OPO's experience in its own service area;

b. Include an analysis of existing barriers to increasing organ donation in the open service area, both internal and external; and

c. Contain a detailed description of specific activities and interventions for increasing organ donation in the open service area.

Many factors can affect organ donation rates. For example, a service area might have a large elderly population, a low motor vehicle accident rate, or a high incidence of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS). It is possible that cultural, ethnic, or racial factors may affect organ donation rates. For example, if there is a large immigrant population in a service area, there might be significant cultural and language barriers to donation. Therefore, an OPO that decided to compete for an open service area might need to perform significant research and data analysis to determine the barriers to increased organ donation in a particular service area. Once this analysis was completed, the OPO's staff would have to develop a detailed description of specific activities and interventions for increasing organ donation in the open service area. Therefore, the development of an acceptable bid would require the diversion of staff resources from the OPO's normal operations.

Full Competition Under Existing Regulations

Under the current Conditions for Coverage for OPOs, there was full competition for each service area at the end of each re-certification cycle (42 CFR 486.316). OPOs that did not meet the performance standards were de-certified and were not able to compete. Therefore, only OPOs that met the performance standards were permitted to compete for service areas.

Benefits of this approach: All other things being equal, greater competition between OPOs should improve performance. If an OPO knows that it is in danger of losing its service area during the recertification process, it should have an incentive to perform well. This incentive would likely cause some OPOs to develop new, innovative practices.

Costs of this approach: As explained above, the process of competing for a service area involves the expenditure of resources. However, there would be little additional effort or resource expenditure for an incumbent OPO to compete for its own area. In addition, full competition is an adversarial process. This may adversely affect the current collaborative atmosphere that exists between the OPOs.

Finally, full competition provides an opportunity for a minimally effective OPO to take over a failing OPO. Depending upon which OPOs competed for a particular service area, however, there is no guarantee that a winning OPO would have more than the minimum requirements to be re-certified, and thus the winning OPO may be unable to improve donation in the service area. Therefore, we are not proposing that OPO service areas be opened to competition from all OPOs. We have not yet quantitatively analyzed

the costs and benefits from this full competition approach, but we will do so for the final rule. However, we are requesting comment on this and other approaches that allow for more intense competition than our preferred option.

Limited Competition

Under this option, all OPO service areas would be open to competition as under the full competition option; however, only those OPOs that met specific criteria would be allowed to compete for another OPO's service area.

The specific criteria used to designate which OPOs would be eligible to compete for another OPO's service area would ensure that the competition was limited to OPOs that had demonstrated above average performance and that OPOs permitted to compete for open service areas would be measurably superior to the incumbent OPOs.

Benefits of this approach: The intent of establishing competition between the OPOs is to improve the overall performance of OPOs by allowing above average OPOs to take over the service areas of poorly or marginally performing OPOs, and to allow OPOs to bid for areas in which they have the potential to significantly outperform the incumbent OPO. The intent is not to have OPOs competing against one another when there are only marginal differences between the OPOs. Therefore, we believe the specific criteria would have to establish a measurable differential. We have not yet quantitatively analyzed the costs and benefits from this limited competition approach, but we will do so for the final rule. However, we are requesting comments on this and other approaches that allow for more intense competition than our preferred option.

Costs of this approach: Although limited competition would require fewer resources from OPOs, the competitive activities would require resources from OPOs that decide to compete for an open service area, especially a large amount of staff time. For OPOs competing for another OPO's service area, these resources would be in addition to those used to improve an OPO's performance in its existing service area.

Although fewer OPOs would be involved with limited competition, it would still be an adversarial process. We anticipate that most OPOs would soon realize who their potential competitors were and this could adversely affect the current collaborative atmosphere that exists between many of the OPOs. Although this effect would be to a much lesser extent than with full competition, the collaborative atmosphere between some OPOs may be adversely affected by limited competition.

Thus, limited competition offers the advantage of having a better performing OPO take over the service area of an incumbent OPO that is not performing as well. It also offers the advantage of setting specific criteria to ensure that the better performing OPO has the expertise to increase organ donation in another service area. This should result in increased organ donation in the competed service area. Further, while limited competition has disadvantages, those disadvantages can be minimized.

Restricted Competition

Under this option, the only competition allowed between OPOs would be for the service areas of OPOs that had been de-certified by CMS. However, the competition would still be limited to OPOs that met specific criteria. The specific criteria would need to ensure that the competing OPOs were more than minimally performing OPOs. The intent would be to have an OPO that is performing measurably better than the de-certified OPO take over the service area.

Benefits of this approach: Limiting competition in this way would restrict competition to areas in which the expectation of significant improvement in service could be met. In addition, fewer resources would be diverted from organ procurement itself to the competitive process.

Costs of this approach: Clearly, restricted competition would severely limit the competition between OPOs. Only service areas of de-certified OPOs would be opened for competition. The service areas of minimally performing OPOs (that is, OPOs whose performance was only slightly above the performance of failing OPOs) would not be opened for competition from OPOs that had performed measurably better. Therefore, restricted competition could not improve organ donation in service areas of minimally performing OPOs.

2. Competition for De-Certified OPO's Service Area

Our preferred option for competing service areas of de-certified OPOs is limited competition, as we feel this option best balances the benefits and costs of the competitive process. However, we are soliciting comments on this conclusion. We propose that a de-certified OPO would not be allowed to compete. The competition would be limited to OPOs that met 4 out of 5 of the outcome performance measures at or above the mean in the preceding re-certification cycle. We would select an OPO for the service area based on its success in meeting the process performance standards, as well as submission of an acceptable plan to increase organ donation in the service.

By requiring an OPO to have attained the mean or greater in 4 out of 5 outcome performance measures in the preceding re-certification cycle, we would limit competition to OPOs that had performed measurably better than the de-certified OPO. We believe such OPOs would have the expertise to take over a poorly performing OPO's service area and improve organ donation. Also, our preferred competition process would require fewer resources from the OPOs than full competition, ensure timely completion of the competitive process, and minimize disruption to operations in service areas.

3. Quadrennial Certification Competition

For the quadrennial certification competition, our preferred option is also limited competition with the following characteristics. We propose that for an OPO to compete for an incumbent OPO's service area, the competing OPO must have achieved at least 100 percent of the mean in 4 out of 5 outcome performance measures in the preceding re-certification cycle. In addition, the competing OPO's conversion rate of potential donors to actual donors must be at least 15 percentage points above the incumbent OPO's conversion rate for the preceding re-certification cycle.

This option offers two clear advantages. First, the competition is limited to at least average performing OPOs because of the requirement that an OPO must have achieved at least 100 percent of the mean in 4 out of 5 outcome performance measures for the preceding re-certification cycle. Second, OPOs permitted to compete for open service areas would be measurably superior to the incumbent OPOs due to the requirement for an OPO to have a conversion rate at least 15 percentage points greater than the conversion rat of the incumbent. These advantages provide us with the assurance that a competing OPO would have the expertise needed to increase organ donation in an incumbent OPO's service area.

This option would restrict the number of OPOs that would be eligible to compete for another OPO's service area. However, we anticipate that there would be a substantial number of OPOs that would qualify to compete.

Under this option, it is possible that a superior performing OPO could compete for the service area of an above average performing OPO. For example,

an OPO that achieved 120 percent of the mean in 4 out of 5 outcome performance measures could compete for the service area of an OPO that achieved 105 percent of the mean in 4 out of 5 outcome performance measures. However, as long as the better-performing OPO could significantly increase organ donation in the open area, we believe it would be worthwhile for the competition to take place.

In determining the necessary differential that would be required to allow competition we had two goals. The first was that we wanted the differential to be large enough to assure us that the competing OPO had the expertise to take over another service area and increase organ donation; in other words, we wanted the differential to reflect significant differences in performance. The second was that we wanted to minimize the disturbance to routine OPO operations that is inherent in the competition process.

We believe that our proposed 15 percentage point differential strikes the balance needed to achieve both of these goals. It is large enough to demonstrate that the competing OPO is performing measurably better than the incumbent OPO. It will also limit the competition to OPOs that we can reasonably expect will be able to take over another service territory and increase organ donation.

Congress clearly intended that a competitive process would reduce uncertainty and result in improved performance by OPOs. We believe that such a competition would result in an increase in organ donation and the number of transplantable organs available for patients on the waiting list. We are specifically soliciting comment, however, on modifications within our chosen limited competition framework. These options are discussed below.

Option 1

Under this option, an OPO competing for an open service area must have achieved at least 120 percent of the mean in 4 out of 5 outcome performance measures for the preceding re-certification cycle. In addition, the competing OPO must have at least a 15 percentage point conversion rate advantage over the incumbent OPO. That is, the competing OPO's conversion rate of potential donors to actual donors (the first of the five performance measures) must be 15 percentage points higher than the incumbent OPO's conversion rate.

This option would ensure that the competing OPO had above average performance and that its performance was measurably superior to the performance of the incumbent OPO. It also would provide us with the assurance that the competing OPO had the expertise to increase organ donation in the incumbent OPO's service area.

We are, however, concerned that this option would severely restrict competition among OPOs because we anticipate that few OPOs would meet 120 percent of the mean for 4 out of 5 performance measures. In addition, since most OPOs would probably be interested only in competing for service areas in their own geographical areas, this could result in virtually no competition in certain areas of the country.

Option 2

As in the first option, option 2 would require that to compete for an incumbent OPO's service area, the competing OPO must have at least a 15 percentage point conversion rate advantage over the incumbent OPO for the preceding re-certification cycle. The advantage of this option is that the competing OPO would be required to demonstrate that it had performed measurably better than the incumbent OPO. While a variation of a few points would not be a reliable indicator of an OPO's superior quality, we believe a 15 percentage point advantage in conversion rate is a large enough difference to assure us that the competing OPO's performance is actually superior to the incumbent OPO's performance.

However, this option would not require an OPO to have achieved a certain level of performance in the outcome performance measures during the prior re-certification cycle. Thus, we are concerned that a 15 percentage point advantage is an insufficient criterion to determine whether or not a competing OPO has the expertise to perform measurably better in the incumbent OPO's service area because, under this option, an OPO that is a below average performer could compete for the service area of a poorly performing OPO. For example, an OPO that achieved 90 percent of the mean in 4 out of 5 outcome performance measures would be permitted to compete for a service area in which the incumbent OPO achieved 75 percent of the mean in 4 out of 5 outcome performance measures. While the 15 percentage point difference indicates that the competing OPO is measurably superior to the incumbent OPO, it does not require that the OPO is at a minimum an average performer.

We are concerned about an OPO with below average performance competing for the service area of another OPO because we do not believe that a OPO that is performing below average in its own service area would have the expertise needed to increase organ donation in another OPO's service area, especially when the incumbent is performing poorly.

In addition, the competitive process itself causes disturbance in the operations of both the competing and incumbent OPOs. Each must develop an acceptable plan for the competition. This requires resources from both OPOs that may have to be diverted from their routine operations, as well as from their efforts to increase organ donation in their service areas. In order to justify the disruption to OPO operations, there should be some assurance that the competing OPO would be able to increase organ donation in the incumbent OPO's service area. With only a 15 percentage point difference and no requirement that the competing OPO be a good performer, we would not feel confident that the competing OPO would have the expertise needed to increase organ donation in the incumbent OPO's service area. Therefore, we believe that if the competing OPO is not at least an average performer, the potential for a slight improvement in the service area would not justify this disruption to the service area.

We also are requesting comments on the option of restricted competition. Under this option, the only competition allowed between OPOs would be for the service areas of OPOs that had been de-certified by CMS. The competition would be limited to OPOs that met 4 out of 5 performance measures at 100 percent of the mean or greater. These specific criteria would ensure that the competing OPOs were more than minimally-performing OPOs and that they were performing measurably better than the de-certified OPO.

Under this option, fewer resources would be diverted from organ procurement itself to the competitive process, and collaboration among OPOs would not be disturbed. However, this option would not allow for competition for the service areas of OPOs that only barely met the qualifications for re-certification.

Cost-Effectiveness and Cost-Benefit Analysis of Preferred Option

Our proposed criteria for selecting a competing OPO are success in meeting the process performance measures during the prior re-certification cycle and an acceptable plan to increase organ donation in the open service area. The minimum requirements for an acceptable plan would be:

- Demonstrate the competing OPO's experience in its own service area;
- Include an analysis of existing barriers to increasing organ donation in the open service area, both internal and external; and
- Provide a detailed description of specific activities and interventions for increasing organ donation in the open service area.

We feel that it would take a competing OPO approximately 16 hours to develop an acceptable plan. A competing OPO would need to assess the incumbent OPO's service area, determine the reasons for or the factors that affected the incumbent's performance, develop an analysis of the existing internal and external barriers to increasing organ donation in the service area, determine the specific activities and interventions the competing OPO can perform to increase organ donation, and finally, prepare and submit the plan.

CMS has not yet fully analyzed the costs and benefits of the alternatives presented above. We expect that the costs per bid assumed in this analysis will be roughly linear as the number of bids increases or decreases based on the allowed level of competition; however, the costs of preparing a bid may depend on local variation in labor rates. We expect that the benefits of competition are not linear; under limited competition, CMS would limit bids only to those situations where we expect that competition will be especially successful in improving performance. We expect that the marginal returns to competition are greater for the more restrictive limited competition options, and that the marginal returns to competition diminish as the options become more permissive. CMS plans to fully analyze the costs and the benefits of the competitive process in the final rule.

Under the statute and current OPO regulations, OPOs must be members of and abide by the rules of the OPTN (as defined in § 486.320); therefore, there is no additional burden associated with this condition.

Current OPO regulations require OPOs to have a board of directors or an advisory board with a specific membership composition. The condition for administration and governing body in this proposed rule might require an OPO to add one additional member to its board. If the tissue banks in the OPO's service area currently are represented on the board by the OPO's own tissue bank, the OPO would be required to add a member from a tissue bank that is not affiliated with the OPO. This condition would also require OPOs to have bylaws to address potential conflicts of interest, length of terms, and criteria for selection and removal of board members. It requires an individual or a governing body to have full legal authority and responsibility for management and provision of all OPO services, including development and implementation of policies and procedures for administration of the OPO.

The economic impact to add a tissue bank member to an OPO board would be negligible because OPOs generally do not pay board members for their services. The economic impact on OPOs that do not have bylaws for their boards addressing conflicts of interest, length of terms, and criteria for selection and removal of board members would be the cost of developing such bylaws. The extent of the impact would depend on the process used to develop the bylaws. For example, at some OPOs, it is likely an executive committee of the board would develop bylaws for approval by the entire board. This process would result in little or no cost to the OPO because the bylaws would be developed by unpaid board members. However, other OPOs might include the OPO director in the development of the bylaws. In this case, there would be a cost to the OPO, based on the number of hours needed to develop the bylaws and the director's salary. We do not expect that development of bylaws would take more than a few hours, since information and advice regarding development of bylaws would be available from OPOs that already have bylaws in place for their boards.

It appears that about 70 percent of OPOs do not have bylaws for their boards addressing conflicts of interest, and approximately 22 percent do not have bylaws addressing length of terms and criteria for selection and removal of board members. This would mean that approximately 18 OPOs would need to develop bylaws addressing conflicts of interest, and approximately 46 would need to develop bylaws addressing length of terms and criteria for selection and removal of board members. Thus, under this proposed rule, OPOs would need to write 64 sets of bylaws for their boards of directors.

In one CMS Consortium, OPO Directors' salaries range from approximately $80,000 to more than $130,000. To estimate the economic impact, we assumed that all OPOs would choose to have their directors participate in developing bylaws for their boards, and that the development of each set of bylaws would take 8 hours of an OPO director's time. If every director made $105,000 per year (approximately $50 per hour), it would cost an OPO $400 to develop a set of bylaws, for a total of $25,600 to develop 64 sets of bylaws. We expect that most, if not all, OPOs currently have an individual or governing body legally responsible for management and provision of OPO services. Therefore, we do not expect that there would be a cost to OPOs to implement this provision of the regulation.

It is extremely difficult to quantify the costs for OPOs of meeting the requirements for human resources. The human resources condition would require every OPO to have a medical director, although it would not specify that the medical director must be full time. We believe all OPOs have medical directors, because the OPTN states that OPOs must have medical directors who are licensed physicians and who are responsible for medical and clinical activities of the OPO. However, our proposal would require the medical director to be involved in the day-to-day operations of the OPO because he or she would be responsible for implementation of protocols for donor evaluation and management and organ placement and recovery, as well as assisting in management of donor cases if the surgeon on call were unavailable.

We believe that nearly all OPOs have a full-time medical director or one or more part-time directors whose responsibilities include implementation of protocols for donor evaluation and management and organ placement and recovery and who assist in the management of donor cases if the surgeon on call is unavailable. These OPOs would already meet the requirements of the proposed rule. In fact, we believe that every OPO in two of the CMS Consortia already fully meet this proposed requirement. However, in a very small number of OPOs, medical directors are not actively engaged in OPO operations; their participation may be limited to consulting and attending board meetings.

It is difficult to quantify the cost to these few OPOs of meeting the proposed requirement because the cost to an individual OPO would be dependent on whether the OPO needed to hire a full-time medical director, hire one or more additional part-time medical directors, or increase the hours of an existing medical director, and to what extent. Furthermore, salaries of medical directors vary widely. Some local transplant surgeons who serve as part-time OPO medical directors do not accept a salary for the services they provide to the OPO; other part-time medical directors are paid up to $100,000 per year. A full-time medical

director may be paid less than $100,000 or as much as $250,000 annually.

To estimate the economic impact of the medical director requirement, we assumed that 10 percent of OPOs (6 OPOs) would need to hire a part-time or full-time medical director or increase the hours of an existing director and that, on average, each of these OPOs would need a medical director for an additional 20 hours per week. If the OPOs reimbursed the medical directors based on a rate of $125,000 annually, it would cost each OPO $62,500, and the total economic impact would be $375,000.

We are also proposing to require an OPO to maintain sufficient staff to carry on essential OPO activities, such as answering hospital referral calls in a timely manner and providing information and support to potential donor families. Most OPOs have sufficient staffing to carry on essential activities; to the extent that they do not, this rule would require them to hire additional staff. However, the impact on individual OPOs would vary, depending upon their situations. For example, all OPOs in one CMS Consortium appear to have sufficient staff to carry on essential activities. In another Consortium, all but two OPOs have sufficient staff. These two OPOs are adding staff based on comparative data from successful OPOs and from the AOPO Annual Report and expect to be staffed fully by mid-2004. However, in a third Consortium, slightly more than half of the OPOs most likely would need one or two procurement coordinators or other professionals in order to have sufficient staff.

Most staff carrying on what would be considered ''essential'' activities (for example, procurement, hospital development, and screening of referral calls) have a medical background. Procurement coordinators are usually registered nurses (RNs), but sometimes they are social workers. In 2000, the median annual income of an RN was $44,840, and the median annual income of medical and public health social workers was $40,020. We have observed that procurement coordinators generally earn about $40,000 to $45,000 to start. Hospital development staff are sometimes RNs and sometimes individuals with public relations backgrounds. In 2000, public relations managers had a median annual income of $54,540. Sometimes OPOs' hospital development and procurement staffs screen referral calls; however, OPOs may hire other individuals to screen calls, such as medical and nursing students or emergency medical technicians. In 2000, emergency medical technicians had a median annual income of $24,460.

We estimate that 10 percent of OPOs (6 OPOs) would need to add one additional professional staff person and 5 percent (3 OPOs) would need to hire 2 additional staff, for a total 12 additional staff. (This estimate includes additional staff needed to meet all proposed requirements except the QAPI requirements, which are discussed later in this preamble.) If each staff person was paid $45,000, the total economic impact would be $540,000.

The human resources condition also would require OPOs to provide the education, training, and supervision to their staffs necessary to furnish required services. We have found that OPOs generally offer three types of staff education and training, depending upon the size and resources of the OPO: (1) On-the-job-training; (2) in-depth training provided within the OPO, sometimes using a modular training structure; and/or (3) classroom training that, in some cases, leads to certification in procurement and transplantation.

Costs for training vary widely; however, we have found that good staff training need not be expensive. OPOs provide no-cost training to each other, in the form of on-site training sessions in hospital development, as well as opportunities for staff details and ''shadowing'' of staff at high-performing OPOs. UNOS Regional Forums, which are held once or twice per year in the 11 UNOS Regions, provide opportunities for staff training at a low cost (for example, $75 per day). Since the training is held within the UNOS Region, travel costs are kept to a minimum. Two OPOs in one of the CMS Regional Consortia have elected to use modular training with demonstration and examination required to move to the next level. Training will be provided to all new and existing OPO professional staff; the cost is estimated at $5000 per OPO. Some OPOs send their procurement coordinators for training provided by the North American Transplant Coordinators Organization, which costs approximately $1000 to $1500 per coordinator.

If we estimate that 25 percent of OPOs (approximately 15 OPOs) would need to provide additional education and training to their professional staff in order to meet the requirements of the proposed rule, and all 15 chose to use in-depth modular training within the OPO, the cost to each OPO would be approximately $5,000, and the total cost for all 15 OPOs would be $75,000.

The human resources condition would require an OPO to have a written policy to address potential conflicts of interest for its director, medical director, senior management, and procurement coordinators. Although we expect that most OPOs have written policies in place, we know that some OPOs do not. If an OPO had to develop such a policy, it is likely it would be developed by the OPO director and would take approximately 8 hours. If the director is paid $105,000 annually (approximately $50 per hour), the cost to the OPO would be approximately $400. If 25 percent of OPOs (approximately 15 OPOs) needed to develop such bylaws, the total economic impact would be $6000.

The human resources condition also would require OPOs to maintain credentialing records for physicians and other practitioners who routinely recover organs in donor hospitals with which the OPO has agreements and ensure that all physicians and other practitioners who recover organs in hospitals are qualified and trained. We have been told by OPOs that most, if not all, OPOs have some type of process to ensure that physicians and other practitioners who recover organs are qualified.

In most cases, organs are recovered by transplant surgeons from the hospital that will perform the transplant or by physicians or technicians employed by or under contract with OPOs. OPOs that do not have a process to ensure that physicians and other practitioners are qualified and trained would incur some costs to put a process into place. An OPO would incur a cost for the staff time needed to request and review credentialing records for transplant surgeons and to request and review documentation of the qualifications of other recovery personnel.

We estimate that requesting and reviewing a record would take no more than 15 minutes. There are approximately 270 hospitals in the United States with transplant programs. Thus, each of the 59 OPOs has, on average, about five transplant hospitals in its service area. If each hospital has 20 surgeons who recover organs, an OPO would have to request and review approximately 100 records. Presuming this activity was performed by an OPO medical director making $125,000 per year ($60 per hour), the cost to the OPO for the medical director to spend 25 hours reviewing 100 records would be $1500. If we estimate that 10 percent of OPOs (approximately 6 OPOs) will need to perform this activity, the total cost would be $9000.

We have not assigned a cost for an OPO to request and review records for physicians or other recovery personnel

who work for or are under contract to the OPO because we assume the OPO would perform those activities in the normal course of business. Likewise, we have not assigned a cost for activities associated with ensuring the qualifications and training of physicians and other recovery personnel from outside an OPO's service area. The time needed to verify qualifications and training of these recovery personnel, who only occasionally recover organs in an OPO's service area, would be minimal and could be accomplished by contacting a transplant hospital to confirm that a surgeon who will recover an organ at one of the OPO's hospitals is credentialed and has privileges at the transplant hospital.

The current OPO regulations require OPOs to maintain donor records with specific data elements, although there is no requirement for how long the records must be kept. The proposed information management condition would require OPOs to include specific data elements in their records and maintain their records for 7 years. We do not anticipate a significant burden associated with this requirement because, the final rule governing the operation of the OPTN state that OPOs must maintain donor records for 7 years; thus, we expect OPOs already meet the proposed requirement.

The condition for reporting of data specifies that an OPO must provide organ donation and transplantation data as requested by the OPTN, the SRTR, and transplant hospitals. Additionally, the OPO would be required to provide data and other information directly to the Department as requested by the Secretary. The current regulations require only that OPOs report five performance data elements to us annually and ''maintain and make available to CMS, the Comptroller General, or their designees data that show the number of organs procured and transplanted.''

Although it appears this requirement has the potential to add a significant new reporting burden, OPOs already report a large amount of data to the OPTN (which, in turn, provides the data to the SRTR for analysis). For example, the cadaver donor registration form that OPOs are required to complete for each donor contains more than 300 data elements. Further, regulations governing the operation of the OPTN at 42 CFR 121.11(b)(2) require OPOs, as specified by the Secretary, to submit data to the OPTN. Thus, most information needed by the OPTN, the SRTR or the Secretary would already be reported by OPOs.

Although it is impossible to quantify the impact of the data reporting requirement, as data would be requested on an as-needed basis, we believe that almost any OPO data needed by us or other agencies within the Department could be obtained from the OPTN or the SRTR. We are including this provision only to give us and other agencies the flexibility to request data from OPOs in the event that needed data cannot be obtained expeditiously from the OPTN or the SRTR. We would not request data from OPOs if the data were readily available from other sources.

However, we can quantify the impact on OPOs of reporting the four hospital-specific data elements they currently report voluntarily to the OPTN (that is, referrals, medically suitable potential donors, consents, and donors). All 59 OPOs have the capability of reporting data to the OPTN electronically. HRSA estimates that reporting the four data elements takes OPOs about 1 hour per month. If the data are entered by a data coordinator earning $40,000 per year (approximately $19.25 per hour), the cost to the OPO would be approximately $231 annually, for a total cost for all 59 OPOs of approximately $13,629.

At the recommendation of the OIG, we are including a requirement for OPOs to report hospital-specific donation data to the public. More than 90 percent of OPOs publish newsletters and annual reports to inform the public of their activities, and, most likely, OPOs will report the hospital data in their newsletters and annual reports at very little additional cost. Since all 59 OPOs maintain Internet sites, they could include the hospital data on their sites at a negligible cost.

There are provisions in the proposed condition for OPOs' relationships with hospitals that do not appear in our current regulations for OPOs. First, the condition would require an OPO to have written agreements with 95 percent of the hospitals and critical access hospitals in the OPO's service area (unless a hospital has a waiver to work with another OPO) that have both a ventilator and an operating room. We expect that OPOs already have agreements with all Medicare and Medicaid hospitals in their service areas (unless a hospital in the service area has a waiver to work with another OPO) because the hospital and critical access hospital CoPs for organ, tissue, and eye procurement (see 42 CFR 482.45 and 485.643), require Medicare and Medicaid participating hospitals and critical access hospitals to have an agreement with an OPO. We have found that most agreements between OPOs and hospitals are ''generic'' in nature and do not specify the OPO and hospital roles in the donation process. However, we propose requiring OPOs to address the responsibilities of both the OPO and the hospital in implementing § 482.45 and § 485.643 and include definitions for the terms ''imminent death'' and ''timely referral.''

Many OPOs would be required to rewrite their agreements; however, we expect OPOs would develop a standard agreement that addresses OPO and hospital responsibilities and defines ''imminent death'' and ''timely death'' and would ask each of their hospitals to sign the standard agreement. We estimate that it would take an attorney 8 hours to draft a new standard agreement that the OPO could present to each hospital. The average hourly wage for an attorney is $40; therefore, the cost to the OPO would be $320. The total cost for all 59 OPOs to have a new standard agreement drafted would be $18,880.

The average OPO has approximately 100 hospitals in its service area. Based on past experience, we expect that between 50 percent and 67 percent of the hospitals in an OPO's service area would sign the standard agreement with no changes. With few exceptions, the remainder of the hospitals would sign the agreements after a minimal amount of negotiation. If 50 hospitals (50 percent of the 100 hospitals in an OPO's service area) requested changes in the agreement before signing, and it took the OPO's attorney 2 hours per agreement to make the changes, it would cost the average OPO $4000. The total cost for all OPOs to make changes in their agreements with hospitals would be $236,000.

The condition also would require OPOs to offer annual designated requestor training to hospital and critical access hospital staffs. Although the hospital and critical access hospital CoPs give OPOs the responsibility for offering or approving designated requestor training for hospitals, very few OPOs have actually provided a significant amount of training to their hospitals. In fact, an August 2000 OIG report (Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule) criticized OPOs for not providing more designated requestor training.

Therefore, complying with this proposed requirement may add some costs for an OPO that has provided little or no designated requestor training if hospitals and critical access hospitals in its service area respond positively to the OPO's offer to provide training. However, we do not anticipate a significant economic impact because most hospitals cannot spare staff to attend training in the entire consent

process and prefer to have their OPO handle most of the consent process. Additionally, although many hospital staff act as designated requestors in a supportive or collaborative role, we expect training for the supportive or collaborative role to be significantly less extensive (and therefore less costly) than training hospital staff for a requestor role. For example, complete designated requestor training might last for 4 to 8 hours, whereas, supporter or collaborator training might last for 2 hours or less. Designated requestor training also may be provided through the use of a videotape. At least one OPO provides designated requestor training over the Internet.

Generally OPO hospital development staff (who are likely to earn about $45,000 per year) provide designated requestor training in hospitals. If the average training session lasts 4 hours and is given at a hospital located 20 miles from the OPO, the total cost of a training session (including salaries for two trainers for preparation, travel, and training time; mileage; and preparing and printing training packets) would be approximately $300. Based on our experience, we expect that nationwide, approximately 75 hospitals might request designated requestor training. Thus, the total economic impact would be approximately $22,500, with an average of less than $400 per OPO.

An OPO would be required to have arrangements to cooperate with tissue banks that have agreements with hospitals with which the OPO has agreements. OPOs would be required to cooperate in screening and referring potential tissue donors, obtaining informed consent on behalf of tissue banks, and in the retrieval, processing, preservation, storage, and distribution of tissues. Most OPOs already have arrangements with the tissue banks in their service areas that address such issues as screening and referral of tissue donors. We are proposing this requirement to address situations in which an OPO has refused to have an arrangement with the tissue bank selected by the hospital.

There are approximately 300 tissue banks in the United States (166 conventional tissue banks and 134 eye banks) or approximately 5 tissue banks per OPO service. In many service areas, the OPO owns or is affiliated with one of the tissue banks. In nearly all service areas, OPOs have arrangements with all tissue banks that have agreements with the hospitals in the service area. Based on our experience, we would expect that fewer than 5 percent of tissue banks (15 tissue banks) that do not have arrangements with an OPO would request an arrangement.

If an OPO and tissue bank elected to have a written agreement, we would expect that the cost to the OPO of preparing the written agreement and making any changes negotiated with the tissue bank would be similar to the costs of preparing and making changes to a written agreement between an OPO and a hospital (that is, a one-time cost to the OPO of $320 for preparing an agreement, and an additional cost of $80 to make changes). However, unlike hospital agreements which could be standardized, we would assume that OPO/tissue bank agreements would be individualized, since it is unlikely that more than one tissue bank in an OPO's service area would request an arrangement. Therefore, the total cost of preparing each agreement and making changes would be $400, and the cost of preparing agreements with 15 tissue banks would be $6000.

For several reasons, we do not believe the proposed requirement to have a QAPI program will have a significant impact on a large number of OPOs. First, as stated earlier in this preamble, most OPOs have a QAPI-type program (although not all programs are sufficiently comprehensive to meet the requirements of the proposed regulation). Second, AOPO is actively encouraging all OPOs to expand and improve their programs; in fact, AOPO recently added the development of a quality improvement program to their requirements for AOPO accreditation, although the new requirements will be phased in over 3 years. Third, in November 2001, AOPO surveyed OPOs to assess its programs and found that 43 percent of the 35 OPOs that responded had designated a staff person whose primary job responsibility was coordinating and monitoring quality improvement. We have reason to believe this percentage would be much higher if the survey were performed today. Since AOPO conducted their survey, the majority of the OPO community has embraced continuous quality improvement and taken steps to integrate quality improvement into their core business structure.

Additionally, there are numerous low-cost or no-cost resources available to OPOs to develop QAPI programs, including the Breakthrough Collaborative, assistance from CMS OPO Coordinators, and the AOPO Quality Council. While we know that some OPOs will be impacted by the proposed QAPI requirement, we do not expect the impact to be significant because, at this time, all OPOs appear to be working toward developing a comprehensive QAPI program.

We believe it is likely that approximately 20 percent of the 59 OPOs (12 OPOs) would need ½ of a full-time equivalent (FTE) position to bring their QAPI programs into compliance with the requirement, and 15 percent (9 OPOs) would need 1 FTE. An OPO would be likely to use an experienced individual from its hospital development or procurement staff, and we estimate that the individual would be paid approximately $50,000 annually. Thus, the cost to each of the 12 OPOs that would need to add ½ of an FTE would be approximately $25,000 per year, and the cost to each of the 9 OPOs that would need to add a full FTE would be $50,000 per year, for a total cost of $750,000.

In addition, the proposed requirement for QAPI would require an OPO to perform death record reviews in every Medicare and Medicaid hospital in its service area that has 150 or more beds or a level I or level II trauma center, with the exception of rehabilitation or psychiatric hospitals. Based on our experience, all OPOs routinely perform death record reviews in hospitals they consider to have significant donor potential, but an OPO's definition of ''significant donor potential'' may not encompass as many hospitals as the requirement in the proposed rule. To the extent that it does not, the OPO might need to increase staff hours to perform the additional death record reviews. We estimate that approximately 20 percent of OPOs (12 OPOs) may need to add ½ of an FTE in order to expand the number of hospitals in which it performs death record reviews. It is likely the death record reviews would be performed by RNs earning approximately $45,000 per year, thus the cost to an OPO of adding ½ of an FTE to perform death record reviews would be approximately $22,500. The total economic impact for all 12 OPOs would be $270,000.

The proposed rule requires that an OPO's QAPI program include a written policy to address adverse events. We estimate that about 90 percent of OPOs (53 OPOs) would need to develop a written adverse event policy and that development of the policy would require 40 staff hours. We expect that the policy would be developed by professional staff, including procurement coordinators, medical directors, and OPO directors. We estimated an annual salary of $45,000 (approximately $22 per hour) for a procurement coordinator, $125,000 (approximately $60 per hour) for a medical director, and $105,000

(approximately $50 per hour) for an OPO director, and we averaged the three hourly rates to arrive at a cost of $44 per staff hour to develop an adverse event policy. Therefore, the cost to one OPO of developing an adverse event policy would be $1760 for 40 hours of work. The total cost to all 53 OPOs that would need to develop such policies would be $93,280.

The condition for requesting consent will have little impact on OPOs. We believe all OPOs have policies for obtaining informed consent and provide training to their staffs in the informed consent process. Under the proposed conditions, some OPOs may have to broaden their informed consent policies, but there will be little resultant economic impact.

The proposed rule would require OPOs to have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor. Based on our experience, all OPOs have written protocols for donor evaluation and management and organ placement and recovery. The OPTN also has model protocols OPOs can follow for evaluation and management of potential donors. Some OPOs might need to update or change their protocols somewhat to meet the proposed requirements, but we believe the cost to individual OPOs would be negligible.

The condition for donor evaluation and management and organ placement and recovery requires the medical director from the OPO to be responsible for ensuring that the OPO has written protocols for donor evaluation and management and for ensuring the implementation of the protocols for each donor. Costs related to hiring or increasing the hours of a medical director are discussed as part of the human resources condition.

This condition also requires OPOs to establish protocols in collaboration with transplant programs that define the roles and responsibilities of the OPO and the transplant program. It appears that all OPOs have some type of agreement or arrangement with the transplant centers in their service areas, but often these agreements or arrangements are informal in nature. Based on our experience, we expect that developing a protocol with a transplant center as required under the proposed rule would take approximately 10 hours. There are approximately 824 transplant programs in the U.S.; therefore, each of the 59 OPOs has approximately 14 transplant programs in its service area. If it took an OPO medical director 10 hours to develop a protocol with a transplant center and the medical director earned a salary of $125,000 annually (approximately $60 per hour), it would cost an OPO $600 for development of a single protocol and a total of $8400 to develop 14 protocols. (We assume that each protocol would be individualized.) If we assume that 70 percent of the 59 OPOs (41 OPOs) needed to develop protocols, the total economic impact would be $344,400.

We foresee little economic impact from the proposed requirements in the condition for organ preparation and transport. We believe nearly all OPOs follow appropriate standards of practice for testing and tissue typing of organs. Developing and following a protocol for packaging, labeling, handling and shipping of organs can be done at very little added cost. For example, the cost of additional supplies for labeling inner and outer packaging of organs with the donor blood type would be negligible.

Our estimates of the economic impact on OPOs to meet the requirements in this proposed rule are as follows.

- $25,600 to develop bylaws for OPO boards
- $375,000 annually for medical director salaries
- $540,000 annually for additional staff to meet human resources requirements
- $75,000 initial cost for staff training
- $6,000 to develop bylaws for OPO directors and other management staff
- $9,000 to develop credentialing records for recovery staff
- $13,629 annually to report data
- $18,880 to develop hospital agreements
- $22,500 for designated requestor training
- $6,000 to develop arrangements with tissue banks
- $750,000 annually for QAPI staff
- $270,000 to perform death record reviews
- $93,280 to develop an adverse event policy
- $344,400 to develop protocols with transplant centers.

Summary of Direct Cost

Therefore, the first-year economic impact would be $2,549,289, and the average first-year cost to each of the 59 OPOs would be $43,208.

Benefits

The primary economic impact of this proposed rule would lie with its potential to increase organ donation. However, it is nearly impossible to predict what that impact will be. Although many in the donation organ community believe that little can be done to increase the number of deceased donors, we would note that in 1998, the year in which the hospital CoP (see § 482.45) went into effect, organ donation increased by nearly 6 percent. Therefore, we estimate that by increasing OPOs' efficiency and adherence to continuous quality improvement measures, the provisions of this proposed rule could increase the number of organ donors by as much as 3 percent per year, resulting in an additional 180 donors in the regulation's first year. Based on 2000 data for the number of organs transplanted per donor (2.87), a 3 percent increase would result in approximately 517 additional transplants in the first year after implementation of the regulation.

Transplants are performed both to save lives and to improve the quality of recipients' lives. For end-stage renal disease patients, dialysis is an alternative to transplantation for extended periods of time. Nevertheless, physical health while on dialysis is significantly impaired, and dialysis imposes major stresses and substantial inconveniences in carrying out normal activities. Therefore, while for most patients, kidney transplantation is not necessary for survival, it significantly improves the quality of the transplant recipient's life. For all other organs, a transplant is, in most cases, necessary for survival.

Of the 17,219 transplants from deceased donors performed in 2000, slightly less than half (46.7 percent), or 8,040, were kidney transplants. Thus, we estimate that in the first year, this regulation could result in approximately 241 (46.7 percent of 517 transplants) lives vastly improved by kidney transplants and 276 (53.3 percent of 517) lives both vastly improved and prolonged by transplantation of other major organs.

The following reasoning was used to construct an estimate of the benefits of this proposed rule. It is common, in cost benefit analysis, to use a concept termed ''value of a statistical life'' (VSL) to estimate in monetary terms the benefits from lives saved. Estimates of this value can be derived from information on the preferences of individuals for reduction in the risk of death, and their willingness to pay for those reductions. For purposes of our cost benefit analysis, we have used a VSL of $5,000,000. Applying this VSL, the social benefit from 276 non-renal transplants would be $1,380,000,000.

Kidney transplantation costs are offset by reductions in other medical costs

over time, primarily dialysis costs. Since private payers generally base their payments on Medicare payment rates, we used data on Medicare payments to estimate the total cost to the economy of the additional non-renal transplants that would be performed. Below, based on 2000 payment data, are 1-year estimated costs to the Medicare program resulting from a 3 percent increase in non-renal organ transplants. Costs for intestinal transplants were not available as Medicare did not begin paying for intestinal transplants until April 2001. However, the number was small—only 36 intestine transplants were performed in the United States in 1999. In addition, the chart does not include heart-lung, kidney-pancreas, and other multi-organ transplants, since complete data are not available for these transplants. In 1999, there were 48 heart-lung, 928 kidney-pancreas, and 120 other multi-organ transplants in the United States, for a total, with intestinal transplants, of 1,132 transplants. Therefore, the figures below underestimate the economic impact of a 3 percent increase in the number of transplants by approximately 14 percent (1,132 is approximately 14 percent of the 15,670 heart, liver, lung, pancreas, and kidney transplants performed in 1999).

ESTIMATED ONE-YEAR COSTS OF NON-RENAL TRANSPLANTS

Organ type	3 percent increase	Cost (inpatient hospital & physician)
Heart	66	$9,277,620
Liver	137	11,227,835
Lung	28	2,012,976
Pancreas	13	357,565
Total	244	22,875,996

In order to estimate the costs of providing post-transplant care, we turned to the Milliman and Robertson 5-year cost estimates that were used by us in the regulation for Medicare and Medicaid hospitals, Identification of Potential Organ, Tissue, and Eye Donors. They are as follows: heart, $317,000; liver, $394,000; lung, $312,000; and pancreas, $149,000. However, note that in recent years, inpatient hospital stays for heart transplant patients have increased considerably (with a resultant rise in costs), whereas inpatient stays for liver transplant patients have decreased considerably. Nevertheless, as Milliman and Robertson estimates are the only transplant data available on post-transplant costs, we used their estimates.

Based on their estimates, the 5-year costs would be as shown on the following chart.

Organ type	5–year cost
Heart	$20,922,000
Liver	53,978,000
Lung	8,736,000
Pancreas	1,937,000
Total	85,573,000

Formal Uncertainty Analysis

As discussed elsewhere in this preamble, our best estimate of the impact of this proposed rule is a benefit of more than $1 billion each year, based on the number of lives we expect would be saved by an increase in organ donation and transplantation due to increased OPO performance. We have not prepared a formal uncertainty analysis for this proposed rule; however, we will prepare a formal uncertainty analysis for the final rule. Possible sources of uncertainty are the actual percentage improvement in organ donation expected by this rule and alternatives; the number of expected total donations, which varies somewhat year to year; the cost of competitive bids; the expected number of OPOs decertified, and the number of OPOs eligible to compete based on their performance measures. We request comments on other potential sources of uncertainty.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 441

Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 486

Health professionals, Medicare, Organ procurement, X-rays.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1138(b), 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, 1395ww, and 1395(x)(v)).

§ 413.200 [Amended]

2. Section 413.200(f) is amended by removing the phrase ''part 485, subpart D'' and by adding ''part 486, subpart D'' in its place.

§ 413.202 [Amended]

3. Section 413.202 is amended by removing the phrase ''as defined in § 435.302 of this chapter'' and by adding ''as defined in § 486.302 of this chapter'' in its place.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

1. The authority citation for part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 441.13 [Amended]

2. Section 441.13(c) is amended by removing the reference ''part 485, subpart D'' and adding ''part 486 subpart G'' in its place.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

1. The authority citation for part 486 is revised to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–g, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

2. Section 486.1 is amended by revising paragraph (a) to read as follows:

§ 486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act:

1102 and 1138(b)—for coverage of organ procurement services.

1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.

1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

* * * * *

3. Part 486 is further amended by revising subpart G to read as follows:

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

Sec.

486.301 Basis and scope.
486.302 Definitions.

Requirements for Certification and Designation

486.303 Requirements for certification.
486.304 Requirements for designation.
486.306 OPO service area size designation and documentation requirements.
486.308 Designation of one OPO for each service area.
486.310 Changes in ownership or service area.

Re-Certification and De-Certification

486.312 De-certification.
486.314 Appeals.
486.316 Re-certification and competition processes.

Organ Procurement Organization Outcome Requirements

486.318 Condition: Outcome measures.

Organ Procurement Organization Process Performance Measures

486.320 Condition: Participation in Organ Procurement and Transplantation Network.
486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.
486.324 Condition: Administration and governing body.
486.326 Condition: Human resources.
486.328 Condition: Reporting of data.
486.330 Condition: Information management.
486.342 Condition: Requesting consent.
486.344 Condition: Donor evaluation and management, and organ placement and recovery.
486.346 Condition: Organ preparation and transport.
486.348 Condition: Quality assessment and performance improvement (QAPI).

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

§ 486.301 Basis and scope.

(a) *Statutory basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization (OPO) must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a ''qualified'' OPO and designation as the OPO for a particular service area.

(2) Section 371(b) of the Public Health Service Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(3) Section 1102 of the Act authorizes the Secretary of Health and Human Services to make and publish rules and regulations necessary to the efficient administration of the functions that are assigned to the Secretary under the Act.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with CMS and the basis for and the effect of termination or non-renewal of the agreement.

(4) The requirements for an OPO to be re-certified for the performance data cycle from January 1, 2002 through December 31, 2005.

§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended recipient.

Agreement cycle refers to the 4-year time period of the agreement between CMS and an OPO. To provide sufficient time for CMS to analyze outcome performance data and assign OPO service areas, the OPO agreement cycle generally begins on August 1 of the year following the end of the re-certification cycle and lasts for 4 years.

Certification means a determination by the Secretary that an OPO meets the requirements at § 486.303 and is eligible for designation if it meets the additional requirements for designation.

Death record review is an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

De-certification means a CMS determination that an OPO no longer meets one or more conditions for coverage, including the outcome measures, the process performance measures and other requirements, or no longer meets the requirements for certification or designation. In addition, if an OPO's agreement with CMS is terminated or is not renewed, the OPO is de-certified.

Designated requestor is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for donation from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

Donor document means any documented indication of an individual's choice in regard to donation that meets the requirements of the governing state law.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan

Area Data Book published by the U.S. Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

Organ donor potential means the number of patients whose age is 70 or less meeting death by neurological criteria, based on generally accepted practice parameters for determining brain death, who do not have any of the following clinical indications:

(1) Tuberculosis.

(2) Creutzfeldt-Jacob Disease or any other prion-induced disease.

(3) Viral septicemia.

(4) Rabies.

(5) Reactive hepatitis B surface antigen.

(6) Any retro virus infection.

(7) Active malignant neoplasms, except primary central nervous system tumors and basal and squamous cell carcinomas.

(8) Aplastic anemia.

(9) Agranulocytosis.

(10) Active viral and systemic fungal infections.

(11) Gangrene of bowel.

(12) Extreme prematurity.

(13) Positive serological or viral culture findings for HIV.

(14) Chagas disease.

Organ procurement organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs.

Potential donor denominator is the basis for the OPO outcome measures. The potential donor denominator indicates the number of individuals in an OPO's service area who meet the criteria for organ donor potential.

Re-certification cycle means the 4-calendar-year cycle of outcome measure data on which an OPO's re-certification is based. The re-certification cycle begins on January 1 and ends (4 years later) on December 31.

Service area means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Transplant hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ transplant centers operating within the same transplant hospital.

Requirements for Certification and Designation

§ 486.303 Requirements for certification.

In order to be certified, an organ procurement organization must:

(a) Have received a grant under 42 U.S.C. 273(a).

(b) Be a non-profit entity that is exempt from Federal income taxation under § 501 of the Internal Revenue Code of 1986.

(c) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals.

(d) Have an agreement with the Secretary to be reimbursed under title XVIII for the procurement of kidneys.

(e) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.

(f) Have procedures to obtain payment for non-renal organs provided to transplant centers.

(g) Agree to enter into an agreement with any hospital or critical access hospital in the OPO's service area, including a transplant hospital, that requests an agreement.

(h) Meet or have met the conditions for coverage, including the outcome measures and the process performance measures and other requirements.

§ 486.304 Requirements for designation.

(a) *Designation is a condition for payment.* Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made to an OPO by a hospital only if the OPO has been designated by the Secretary as an OPO.

(b) *Requirements for designation.* An OPO must do the following:

(1) Be certified as a qualified OPO by the Secretary under 42 U.S.C. 273(b) and § 486.303.

(2) Enter into an agreement with CMS that meets the requirements set forth in paragraph (c) of this section.

(3) Document that it has a defined service area that meets the requirements of § 486.306.

(c) *Agreement with CMS.* In order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid, an OPO must enter into an agreement with CMS. The agreement is effective upon submission by the OPO and acceptance by CMS but may be canceled by either party. If an OPO is de-certified under § 486.312, payment for organ procurement services attributable to that OPO will not be made for services furnished on or after the effective date of the de-certification. In the agreement, the OPO must agree to do the following:

(1) Maintain compliance with the requirements of titles XVIII and XIX of the Act, section 1138 of the Act, section 371(b) of the Public Health Service Act, and applicable regulations, including the conditions set forth in this subpart and the rules and requirements of the OPTN, as defined by § 486.320, and to report promptly to the Secretary any failure to do so.

(2) Become a member of the OPTN.

(3) File a cost report in accordance with § 413.24(f) of this chapter within 5 months after the end of each fiscal year.

(4) Permit CMS to designate an intermediary to determine the interim payment rate payable to transplant hospitals for services provided by the OPO and to make a determination of reasonable cost based on the cost report in the OPO files.

(5) Provide budget or cost projection information as may be required to establish an initial interim payment rate.

(6) Pay to CMS amounts that have been paid by CMS to transplant hospitals as Medicare payment for organ recovery fees that are determined to be in excess of the reasonable cost of the services provided by the OPO.

(7) Not charge an individual for items or services for which that individual is entitled to have payment made under the Medicare program.

(d) *Application for designation.* An OPO that has met 4 out of 5 outcome performance measures at or above the mean for the previous re-certification cycle may apply for designation for the service area of an OPO that did not meet the conditions for coverage for the previous re-certification cycle. An OPO that has met 4 out of 5 outcome performance measures at 100 percent of the mean may apply for designation whenever a service area becomes an open area if the OPO's conversion rate of potential donors to actual donors is at least 15 percentage points greater than the conversion rate of the OPO currently designated for the service area.

(e) *Designation periods—*

(1) *General.* An OPO is normally designated for 4 years. A designation period may be shorter, for example, an interim designation for the service area of an OPO that has terminated its

agreement with CMS. A designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to an OPO that has been de-certified.

(2) *Re-designation.* Re-certification and re-designation must occur not more frequently than every 4 years.

§ 486.306 OPO service area size designation and documentation requirements.

(a) *General documentation requirement.* An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) *Service area designation.* The defined service area either includes an entire metropolitan statistical area or a New England county metropolitan statistical area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) *Service area location and characteristics.* An OPO must define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area.

(3) The number of and the names of all hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

(d) It must procure organs from an average of at least 24 donors per calendar year in the 4 years before the year of re-designation.

§ 486.308 Designation of one OPO for each service area.

(a) CMS designates only one OPO per service area. A service area is open for competition once the existing designation period has expired or when the existing designated status of the OPO for the service area has been terminated.

(b) Unless CMS has granted a hospital a waiver under paragraphs (d) through (f) of this section, the hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located.

(c) If CMS changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (d) of this section within 30 days of notice of the change in designation.

(d) A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to CMS establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients listed for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(e) In making a determination on waiver requests, CMS considers—

(1) Cost effectiveness;

(2) Improvements in quality;

(3) Changes in a hospital's designated OPO due to changes in the definitions of metropolitan statistical areas, if applicable; and

(4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(f) A hospital may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

§ 486.310 Changes in ownership or service area.

(a) *OPO requirements.* (1) A designated OPO considering a change in ownership or in its service area must notify CMS before putting it into effect. This notification is required to ensure that the OPO, if changed, will continue to satisfy Medicare and Medicaid requirements. The merger of one OPO into another or the consolidation of one OPO with another is considered a change in ownership.

(2) A designated OPO considering a change in its service area must obtain prior CMS approval. In the case of a service area change that results from a change of ownership due to merger or consolidation, the OPOs must resubmit the information required in an application for designation. The OPO must provide information specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation CMS determines to be necessary for designation.

(b) *CMS requirements.* (1) If CMS finds that the OPO has changed to such an extent that it no longer satisfies the requirements for OPO designation, CMS may de-certify the OPO and declare the OPO's service area to be an open area. An OPO may appeal such a de-certification as set forth in § 486.314. The OPO's service area is not opened for competition until the conclusion of the appeals process.

(2) If CMS finds that the changed OPO continues to satisfy the requirements for OPO designation, the period of designation of the changed OPO is the remaining portion of the 4 year term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is the longest of the remaining periods unless CMS determines that a shorter period is in the best interest of the Medicare and Medicaid programs. The changed OPO must continue to meet the process performance measures and other requirements at § 486.20 through § 486.48 throughout the remaining period and must meet the outcome measures at § 486.318 at the end of this remaining period.

Re-Certification and De-Certification

§ 486.312 De-certification.

(a) *De-certification due to voluntary termination of agreement.* If an OPO wishes to terminate its agreement, it must send written notice of its intention to terminate its agreement and the proposed effective date of the termination to CMS. CMS may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if it determines that a different date would not disrupt services to the service area or otherwise interfere with the effective and efficient administration of the Medicare and Medicaid programs. If CMS determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by CMS. CMS will de-certify the OPO as of the effective date of the voluntary termination.

(b) *De-certification due to involuntary termination of agreement.* CMS may terminate an agreement with an OPO if CMS finds that the OPO no longer meets the requirements for designation or certification or the conditions for coverage in this subpart or is not in substantial compliance with any other applicable Federal regulations or provisions of titles XI, XVIII, or XIX of the Act. CMS may also terminate an

agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will de-certify the OPO as of the effective date of the involuntary termination.

(c) *De-certification due to non-renewal of agreement.* CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the condition for coverage at § 486.318 based on data from the most recent re-certification cycle or if the OPO's designation has been terminated. CMS will de-certify the OPO as of the ending date of the agreement.

(d) *Notice to OPO.* Except in cases of urgent need, CMS gives written notice of de-certification to an OPO at least 90 days before the effective date of the de-certification. In cases of urgent need, CMS gives written notice of de-certification at least three calendar days prior to the effective date of the de-certification. The notice of de-certification states the reason for de-certification and the effective date.

(e) *Public notice.* Once CMS approves the date for a voluntary termination, the OPO must provide prompt public notice of the date of de-certification and such other information as CMS may require through publication in local newspapers in the service area. In the case of involuntary termination or non-renewal of an agreement, CMS provides public notice of the date of de-certification through publication in local newspapers in the service area. No payment under title XVIII or title XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the date the de-certification is effective.

§ 486.314 Appeals.

If an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive or procedural grounds.

(a) *Appeal process.* The OPO must file its appeal within 30 calendar days of the date of the notice of de-certification. In its appeal, the OPO may submit evidence to demonstrate why it should not be de-certified. Within 2 weeks of receipt of the OPO's appeal, a CMS hearing officer will schedule a hearing. The hearing officer will issue notice of his or her decision to the OPO by certified mail within 2 weeks of the hearing.

(b) *Reversal of de-certification.* If the hearing officer reverses CMS' determination to de-certify an OPO in a case involving the involuntary termination of the OPO's agreement, CMS will not terminate the OPO's agreement and will not de-certify the OPO at that time.

(c) *De-certification is upheld.* If the de-certification determination is upheld by the hearing officer, Medicare and Medicaid payment may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. There are no further administrative appeal rights.

(d) *Effects of de-certification.* When an OPO agreement is terminated or is not renewed, CMS will accept applications from other OPOs to be designated for the open area as set forth in § 486.316(b). An OPO that is de-certified may not apply or be designated for an open area.

(e) *Extension of agreement.* If there is insufficient time prior to expiration of an agreement with CMS to allow for competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose to extend the OPO's agreement with CMS for a period not to exceed an additional 60 days.

§ 486.316 Re-certification and competition processes.

CMS opens all OPO service areas for competition at the end of every re-certification cycle.

(a) *OPO meets conditions for coverage.* When an OPO meets the outcome measures in § 486.318 and has been found to be in compliance with the process performance measures and other requirements in §§ 486.320 through 486.348, CMS will open the OPO's service area for competition. An OPO may compete for the open area only if it met 4 out of 5 outcome measures at or above 100 percent of the mean for the preceding re-certification cycle and its conversion rate of potential donors to actual donors is at least 15 percentage points higher than the conversion rate of the OPO currently designated for the service area. The OPO must compete for the entire service area. The incumbent OPO may compete for its own service area.

(b) *OPO does not meet conditions for coverage.* If CMS notifies an OPO that it will be de-certified because its agreement will not be renewed or will be terminated by CMS, and the OPO does not appeal within the time frame specified in § 486.314(a) or the OPO's de-certification is upheld on appeal, CMS will open the OPO's service area for competition from other OPOs. An OPO may compete for the open service area only if it met 4 out of 5 outcome measures at or above the mean for the preceding re-certification cycle. The OPO must compete for the entire area.

(c) *Criteria for selection.* CMS will designate an OPO for an open service area based on the competing OPOs' degree of success in meeting the process performance measures during the preceding re-certification cycle and the submission of an acceptable plan to increase organ donation in the open service area. An acceptable plan to increase organ donation, at a minimum—

(1) Is based on the competing OPO's experience and success in its own service area;

(2) Includes an analysis of existing barriers, both internal and external, to increasing organ donation in the open area; and

(3) Provides a detailed description of specific activities and interventions for increasing organ donation in the open service area.

(d) *No OPO applies.* If no OPO applies to compete for the open area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS will make its decision based on the OPOs' success in meeting the process performance measures during the preceding re-certification cycle.

Organ Procurement Organization Outcome Requirements

§ 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in non-contiguous U.S. States, U.S. territories, U.S. possessions, or U.S. commonwealths, an OPO must achieve at least 75 percent of the national mean in 4 of the 5 following performance categories, averaged over the 4 calendar years before the year of re-certification:

(1) Donors, as a percentage of the potential donor denominator.

(2) Number of kidneys procured, as a percentage of the potential donor denominator.

(3) Number of kidneys transplanted, as a percentage of the potential donor denominator.

(4) Number of extra-renal organs procured, as a percentage of the potential donor denominator.

(5) Number of extra-renal organs transplanted, as a percentage of the potential donor denominator.

(b) An OPO operating exclusively in non-contiguous U.S. States, U.S. territories, U.S. possessions, or U.S. commonwealths must meet the following outcome measures at 50 percent or more of the national mean, averaged over the 4 calendar years before the year of re-certification:

(1) Number of kidneys procured, as a percentage of the potential donor denominator.

(2) Number of kidneys transplanted, as a percentage of the potential donor denominator.

Organ Procurement Organization Process Performance Measures

§ 486.320 Condition: Participation in Organ Procurement and Transplantation Network.

After being designated, an OPO must become a member of and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term ''rules and requirements of the OPTN'' means those rules and requirements approved by the Secretary. No OPO is considered out of compliance with section 1138(b)(1)(D) of the Act or this section until the Secretary approves the determination that the OPO failed to comply with the rules and requirements of the OPTN. The Secretary may impose sanctions under section 1138 only after such non-compliance has been determined in this manner.

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

(a) *Standard: Hospital agreements.* An OPO must have a written agreement with 95 percent of the hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to the requirements for hospitals at § 482.45 or § 485.643 and specify the meaning of the terms ''timely referral'' and ''imminent death.''

(b) *Standard: Designated requestor training for hospital staff.* The OPO must offer designated requestor training on at least an annual basis for hospital and critical access hospital staff.

(c) *Standard: Cooperation with tissue banks.* (1) The OPO must have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:

(i) Screening and referral of potential tissue donors.

(ii) Obtaining informed consent from families of potential tissue donors.

(iii) Retrieval, processing, preservation, storage, and distribution of tissues.

(2) An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO.

§ 486.324 Condition: Administration and governing body.

(a) While an OPO may have more than one board, the OPO must have an advisory board that has both the authority described in paragraph (b) of this section and the following membership:

(1) Members who represent hospital administrators, voluntary health associations in the OPO's service area, and either intensive care or emergency room personnel.

(2) An individual from a tissue bank who represents all tissue banks that have agreements with hospitals with which the OPO has agreements (if such an individual is available to serve on the board). The individual must be from a tissue bank not affiliated with the OPO, unless the only tissue bank in the service area is affiliated with the OPO.

(3) Individuals who represent the public residing in the OPO's service area.

(4) A physician with knowledge, experience, or skill in the field of human histocompatibility or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

(5) A neurosurgeon or other physician with knowledge or skills in neurosciences.

(6) A transplant surgeon representing each transplant hospital in the service area with which the OPO has arrangements to coordinate its activities. The transplant surgeon must have practicing privileges and perform transplants in the transplant hospital represented.

(b) The advisory board described in paragraph (a) of this section has the authority to recommend policies for the following:

(1) Procurement of organs.

(2) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation.

(3) Systematic efforts, including professional education, to acquire all useable organs from potential donors.

(4) Arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.

(5) Appropriate tissue typing of organs.

(6) A system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in § 486.320 of this part.

(7) Transportation of organs to transplant hospitals.

(8) Coordination of activities with transplant hospitals in the OPO's service area.

(9) Participation in the OPTN.

(10) Arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors.

(11) Annual evaluation of the effectiveness of the OPO in acquiring organs.

(12) Assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) The advisory board described in paragraph (a) of this section has no authority over any other activity of the OPO and may not serve as the OPO's governing body or board of directors. Members of the advisory board described in paragraph (a) of this section are prohibited from serving on any other OPO board.

(d) The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members.

(e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(f) The OPO must have a procedure to address potential conflicts of interest for the governing body described in paragraph (e) of this section.

§ 486.326 Condition: Human resources.

All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital

development staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.

(a) *Standard: Qualifications.* (1) The OPO must ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services.

(2) The OPO must develop and implement a written policy that addresses potential conflicts of interest for the OPO's director, medical director, and senior management, and procurement coordinators.

(3) The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO and ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained.

(b) *Standard: Staffing.* (1) The OPO must provide sufficient coverage, either by its own staff or under contract or arrangement, to assure both that hospital referral calls are screened for donor potential and that potential donors are evaluated for medical suitability in a timely manner.

(2) The OPO must have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of the donor, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development.

(3) The OPO must provide a sufficient number of recovery personnel, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation.

(c) *Standard: Education, training, and performance evaluation.* The OPO must provide its staff with the education, training, and supervision necessary to furnish required services. Training must include but is not limited to performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. OPOs must evaluate the performance of their staffs and provide training, as needed, to improve individual and overall staff performance and effectiveness.

(d) *Standard: Medical director.* The OPO's medical director is responsible for implementation of the OPO's protocols for donor evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

§ 486.328 Condition: Reporting of data.

(a) The OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data to the OPTN and the Scientific Registry of Transplant Recipients (SRTR), as directed by the Secretary. The OPO must provide hospital-specific organ donation data to transplant hospitals, annually. The OPO must report individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Department, as requested by the Secretary. The data may include, but are not limited to—

(1) Number of hospital deaths;

(2) Results of death record reviews;

(3) Number and timeliness of referral calls from hospitals;

(4) Potential donor denominator (as defined in § 486.302);

(5) Data related to non-recovery of organs;

(6) Data about consents for donation;

(7) Number of donors;

(8) Number of organs recovered (by type of organ); and

(9) Number of organs transplanted (by type of organ).

(b) The potential donor denominator data reported to the OPTN to be used for OPO re-certification must include data for all deaths that occurred in hospitals and critical access hospitals in the OPO's service area, unless a hospital or critical access hospital has been granted a waiver under 486.308(d) to work with a different OPO. Data reported by the OPO to the OPTN must be reported within 30 days after the end of the month in which a death occurred. If an OPO determines through death record review or other means that the potential donor denominator data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN within 30 days of the end of the month in which the mistake is identified.

(c) For the purpose of determining the information to be collected under paragraph (a) of this section, the following definitions apply:

(1) Kidneys procured. Each kidney recovered will be counted individually. En bloc kidneys recovered will count as two kidneys procured.

(2) Kidneys transplanted. Each kidney transplanted will be counted individually. En bloc kidney transplants will be counted as two kidneys transplanted.

(3) Extra-renal organs procured. Each organ recovered is counted individually.

(4) Extra-renal organs transplanted. Each organ or part thereof transplanted will be counted individually. For example, a single liver is counted as one organ procured and each portion that is transplanted will count as a transplant. Further, a heart and double lung transplant will be counted as three organs transplanted. A kidney/pancreas transplant will count as one kidney transplanted and one extra-renal organ transplanted.

(d) The OPO must report hospital-specific organ donation data, including organ donor potential and the number of donors, to the public at least annually.

§ 486.330 Condition: Information management.

An OPO must establish and use an information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop and follow procedures to ensure the confidentiality and security of the information.

(a) *Donor information.* The OPO must maintain a record for every donor. The record must include, at a minimum, information identifying the donor (for example, name, address, date of birth, social security number or other unique identifier, such as Medicare health insurance claim number), organs and (when applicable) tissues recovered, date of the organ recovery, donor management data, all test results, current hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information.

(b) *Disposition of organs.* The OPO must maintain records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant recipients.

(c) *Data retention.* Donor and transplant recipient records must be maintained in a human readable and reproducible paper or electronic format for 7 years.

(d) *Format of records.* The OPO must maintain data in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and

transplant recipient records and procedural manuals and other materials used in conducting OPO operations.

§ 486.342 Condition: Requesting consent.

An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families.

(a) An OPO must have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. The OPO must provide to the individual(s) responsible for making the donation decision, at a minimum, the following:

(1) A list of the organs or tissues that may be recovered.

(2) All possible uses for the donated organs or tissues.

(3) The information that the individual(s) have the right to limit or restrict use of the organs or tissues.

(4) A description of the screening and recovery processes.

(5) Information (such as for-profit or non-profit status) about organizations that will recover, process, and distribute the tissue.

(6) Information regarding access to and release of the donor's medical records.

(7) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body.

(8) Information about the procedure for filing a complaint.

(9) Contact information in case the individual(s) making the donation decision have questions.

(10) A copy of the signed consent form if a donation is made.

(b) If an OPO does not request consent to donation because a potential donor consented to donation before his or her death in a manner that satisfied applicable State law requirements in the potential donor's State of residence, the OPO must provide information about the donation to the family of the potential donor, as requested.

§ 486.344 Condition: Donor evaluation and management and organ placement and recovery.

The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

(a) *Donor protocol management.* (1) The medical director is responsible for ensuring that donor evaluation and management protocols are implemented correctly and appropriately to ensure that every potential donor is thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

(2) The OPO must implement a system that ensures the medical director or other qualified physician is available to assist in the medical management of a donor when the surgeon on call is unavailable.

(b) *Evaluation.* The OPO must do the following:

(1) Verify that death has been pronounced according to applicable local, state, and federal laws pertaining to organ donation.

(2) Determine whether there are conditions that may contraindicate donation.

(3) If possible, obtain the potential donor's medical and social history.

(4) Review the potential donor's medical chart and perform a physical examination of the donor.

(5) Obtain the donor's vital signs and perform all pertinent tests.

(c) *Testing.* The OPO must do the following:

(1) Arrange for screening and testing of the donor for infectious disease according to current standards of practice, including testing for the human immunodeficiency virus.

(2) Ensure that screening and testing of the donor (including point-of-care testing and blood typing) are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(3) Ensure that the donor's blood is typed using two separate blood samples.

(4) Document the donor's record with all test results, including blood type, before organ recovery.

(d) *Standard: Collaboration with transplant programs.* (1) The OPO must establish protocols in collaboration with transplant programs that define the roles and responsibilities of the OPO and the transplant program for all activities associated with donor evaluation, donor management, organ recovery, and organ placement. The protocol for organ placement must include procedures to ensure that the blood type of the donor is compared with the blood type of the intended recipient by two OPO staff members before organ recovery takes place and that documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.

(2) The established protocols must be reviewed periodically with the transplant programs to incorporate best practices in the field and maximize organ donation.

(e) *Documentation of recipient information.* Prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended recipient's position on the waiting list in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

(f) *Organ allocation.* The OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in § 486.320 of this part.

(g) *Organ placement.* The OPO must develop and implement a protocol to maximize placement of organs for transplantation.

§ 486.346 Condition: Organ preparation and transport.

(a) The OPO must arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO must ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(b) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor's management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. Two OPO staff members must verify that the documentation that accompanies an organ to a transplant center is correct.

(c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ or health of the recipient. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two OPO staff members that information listed on the labels is correct.

(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor's blood type.

§ 486.348 Condition: Quality assessment and performance improvement (QAPI).

The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all

donation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) Standard: Death record reviews. As part of its ongoing QAPI efforts, an OPO must conduct death record reviews in every Medicare and Medicaid participating hospital in its service area that has a level I or level II trauma center or 150 or more beds (unless the hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals. When missed opportunities for donation are identified, the OPO must implement actions to improve performance.

(c) *Standard: Adverse events.* (1) An OPO must establish a written policy to address adverse events that occur during any phase of an organ donation case. The policy must address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events.

(2) The OPO must conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO's policies and practices to prevent repeat incidents.

(3) The OPO must—

(i) Report an adverse event to CMS within 10 business days of becoming aware of the adverse event; and

(ii) Provide to CMS written documentation of the investigation and analysis of the adverse event within 15 business days of becoming aware of the event.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

1. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 498.2 [Amended]

2. In § 498.2, the definition of ''Supplier'' is amended by removing ''organ procurement organization (OPO),''.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Editorial Note: This document was received in the Office of the Federal Register on January 26, 2005.

Approved: July 29, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–1695 Filed 1–28–05; 8:45 am]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 482, and 488

Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 405, 482, and 488

[CMS–3835–P]

RIN 0938–AH17

Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth the requirements that heart, heart-lung, intestine, kidney, lung, and pancreas transplant centers must meet to participate as Medicare-approved transplant centers. These proposed revised requirements focus on an organ transplant center's ability to perform successful transplants and deliver quality patient care as evidenced by good outcomes and sound policies and procedures. We are proposing that approval, as determined by a center's compliance with the proposed data submission, outcome, and process requirements would be granted for 3 years. Every 3 years, approvals would be renewed for transplant centers that continue to meet these requirements. We are proposing these revised requirements to ensure that transplant centers continually provide high-quality transplantation services in a safe and efficient manner.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 5, 2005.

ADDRESSES: In commenting, please refer to file code CMS–3835–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3835–P, PO Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or

7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Eva Fung (410) 786–7539. Marcia Newton (410) 786–5265. Jeannie Miller (410) 786–3164. Rachael Weinstein (410) 786–6775.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3835–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public website as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Key Statutory Provisions

The Medicare statute contains specific authority for prescribing the health and safety requirements for facilities furnishing end stage renal disease (ESRD) care to beneficiaries, including renal transplant centers, pursuant to section 1881(b)(1) of the Social Security Act (the Act). Section 1102 of the Act (42 U.S.C. 1302) authorizes the Secretary to publish rules and regulations ''necessary for the efficient administration of the functions'' with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to ''prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title.'' In 2003, 13,278 donors (deceased and living) provided organs in the U.S., and 25,468 transplants (deceased and living donor) were performed, yet 83,731 patients waited for a transplant at the end of 2003. Given the relative scarcity of donated organs compared to the number of people on transplant waitlists and the critical need to use these limited resources efficiently, we believe the proposed conditions of participation (CoPs) for transplant centers are necessary to: (1) Protect other potential Medicare beneficiaries who are waiting for organs for transplantation; (2) establish sufficient quality and procedural standards to ensure that transplants are performed in a safe and efficient manner; and (3) reduce Medicare expenses by decreasing the likelihood that a transplant will fail.

Section 1864 of the Act authorizes the use of State agencies to determine providers' compliance with the CoPs. Responsibilities of States in ensuring compliance with the CoPs are set forth in regulations at 42 CFR part 488, Survey, Certification, and Enforcement Procedures. Under section 1865 of the Act and § 488.5 of the regulations,

hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are not routinely surveyed by State agency surveyors for compliance with the conditions but are deemed to meet most of the requirements in the hospital CoPs based on their accreditation. In order to receive deemed status, hospitals accredited by the JCAHO, the AOA, or other national accreditation programs with deeming authority under § 488.6 of the regulations must meet requirements that are at least as stringent as the Medicare CoPs. (*See* Part 488, Survey and Certification Procedures.) Therefore, an accreditation organization could apply for and receive approval of deeming authority for the proposed hospital CoPs for transplant centers if the accreditation organization demonstrates that it has requirements for transplant centers that are at least as stringent as the proposed CoPs.

B. Department Activities Related to Organ Donation and Transplantation

1. Department Commitment To Increasing Organ Donation and Transplantation

At the end of 2003, there were 83,731 Americans waiting for organ transplants. About 25,468 patients on the waitlist received organ transplants (deceased and living donor), and approximately 6,879 persons died waiting for an organ to become available. Promotion of organ donation, which would increase the number of transplant recipients by increasing organ availability, is of paramount importance to the Department of Health and Human Services (the Department). On April 17, 2001, Secretary Tommy Thompson launched his ''Gift of Life Donation Initiative,'' a multi-level approach to increasing organ, tissue, and marrow donation. The Secretary has directed agencies within the Department to make organ, tissue, and marrow donation a top priority. The Secretary's initiative focuses on 5 elements: (1) A model donor card program, (2) a national forum on donor registries, (3) a national ''Gift of Life'' medal to honor donor families, (4) a model curriculum on organ donation for drivers' education classes, and (5) the ''Workplace Partnership for Life'' program, which involves collaboration with companies and employer groups to make information on organ donation available to all employees.

We are revising the current Medicare requirements for heart, intestine, kidney, liver, and lung centers and adding new Medicare requirements for heart-lung and pancreas centers by proposing transplant center hospital conditions of participation. The proposed CoPs would ensure that all Medicare-approved transplant centers provide quality transplantation services so that organs, once recovered, are not wasted. This proposed rule would not apply to the Medicaid program.

2. Transplantation Criteria Town Hall Meeting

We held a Town Hall Meeting on December 1, 1999 (*See* 64 FR 58419) to discuss current medical and scientific evidence regarding potential criteria for approval of transplant centers for Medicare coverage. Approximately 150 people attended the meeting. Attendees included representatives from the Organ Procurement and Transplantation Network (OPTN), staff from transplant centers, health policy and clinical researchers, transplant recipients and their families, physicians and other clinicians, and government officials.

The format for the meeting included four subject-related panel presentations followed by an opportunity for comments from the attendees. The panel topics included: (1) Aspects of facilities linked to coverage, (2) methodologies for measuring outcomes, (3) data used for approving centers, and (4) thresholds for approving centers. In addition to the planned panel topics, the meeting provided for an open forum during which ideas not covered in the topic panels could be shared. To accommodate the views of those who could not attend the meeting, we provided an opportunity for members of the community to share their views in writing.

Comments from the Town Hall Meeting expressed widely divergent views. However, the ideas shared during this meeting and the written public comments were considered seriously and significantly influenced the development of this proposed rule. Our staff has also attended meetings, conferences and training to stay abreast of the latest advancement and issues associated with transplantation.

C. Current Medicare Policy Regarding Transplantation

1. Kidney Transplant Centers

Section 1881 of the Act authorizes benefits for individuals who have been determined to have ESRD, including dialysis and transplantation services. Section 1881(b)(1)(A) of the Act provides an explicit direction to the Secretary of Health and Human Services to develop requirements for kidney (renal) transplantation services under the Medicare program. We fulfilled this responsibility through regulations published on June 3, 1976 (41 FR 22511). These requirements are codified at 42 CFR part 405, Subpart U. Under the Conditions for ESRD coverage, renal transplant centers must meet all appropriate conditions of coverage, which address issues such as compliance with applicable Federal, State, and local laws and regulations; Governing body; Patient long-term program and patient care plan; Patients' rights; Medical records; and Physical environment. In addition, the conditions of coverage include the following criteria specifically for kidney or renal transplant centers:

- *Minimum utilization rates.* The regulations classify renal transplant centers that meet all the other conditions for coverage of ESRD services at 42 CFR 405, Subpart U into the following 4 categories according to the center's minimum utilization rates (annual volume): (1) Unconditional status, (2) conditional status, (3) exception status, and (4) not eligible for reimbursement for that ESRD service. (*See* 42 CFR 405.2122.) Unconditional status is assigned to a center that performs 15 or more transplants per year. Conditional status is assigned to a center that performs 7 to 14 transplants per year. (*See* 42 CFR 405.2130.) If a center does not meet the minimum utilization rate for unconditional or conditional status, it may, under certain circumstances, be approved for a time-limited exception status. A center that does not meet the requirements for conditional or unconditional status and is not granted an exception status under § 405.2122(b) is not eligible for reimbursement for that ESRD service. (*See* 42 CFR 405.2122.)

- *Director of Renal Transplantation.* Renal transplant centers must be under the direction of a qualified transplant surgeon or a physician who is responsible for: (1) Participating in the selection of suitable treatment modalities for each ESRD patient; (2) ensuring adequate training of nurses in the care of transplant patients; (3) ensuring tissue typing and organ procurement services are available either directly or under arrangement; and (4) ensuring transplantation surgery is performed under the direct supervision of a qualified transplant surgeon (*See* 42 CFR 405.2170).

- *Minimal Service Requirements.* Renal transplant centers must meet the following minimal service requirements: (1) Be part of a Medicare-approved and participating hospital; (2) be under the supervision of the hospital administrator and medical staff; (3)

participate in a patient registry program with an OPO for patients who are awaiting deceased donor transplantation; (4) utilize a qualified social worker to evaluate transplant patients' psychosocial needs, participate in care planning of the patients and identify community resources to assist the patient and family; (5) utilize a qualified dietitian who will, in consultation with the attending physician, assess the nutritional and dietetic needs of each patient, recommend therapeutic diets, provide diet counseling to patients and their families, and monitor adherence and response to a prescribed diet; (6) utilize a laboratory that is approved under 42 CFR Part 493 and that can perform cross-matching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique on a 24-hour emergency basis, and (7) utilize the services of an organ procurement organization (OPO) to obtain deceased donor organs, and have a written agreement covering the services (See 42 CFR 2171).

Even though the ESRD conditions of coverage contained at 42 CFR part 405, subpart U include some kidney transplant center provisions, the proliferation of patient and living donor issues and our desire to standardize requirements for transplant centers necessitate a broader regulatory framework for the oversight of kidney transplant centers. Therefore, we have concluded that it is logical for us to replace the requirements contained in Part 405, Subpart U that pertain solely to renal transplant centers with approval and re-approval requirements for kidney transplant centers in these proposed hospital CoPs for organ transplant centers. Specifically, we propose to delete § 405.2120 through § 405.2134, § 405.2170 through § 405.2171, and the definitions for ''histocompatibility testing,'' ''ESRD Network,'' ''Network organization,'' ''organ procurement,'' ''renal transplantation center,'' ''transplantation service,'' and ''transplantation surgeon'' contained in § 405.2102. The proposed transplant center CoPs are both outcome and process-based and would collectively ensure that transplantation services furnished in all types of transplant centers are safe and efficient.

Generally, the provisions contained in the proposed transplant center CoPs are applicable to all types of transplant centers. However, kidney transplantation differs from other types of organ transplants in some ways. For example, section 1881(b)(1)(A) of the Act explicitly provides for Medicare kidney transplants while coverage of most transplant services are provided under the general ''reasonable and necessary'' authority of section 1862. Also, whereas organ transplantation is the only treatment option for patients with end-stage heart, liver, lung or intestinal failure, dialysis is an alternative treatment for ESRD patients when transplantation is not feasible. To underscore the distinct nature of kidney transplants and kidney transplant centers, we have included some provisions that are specific only to kidney transplant centers in the proposed hospital CoPs for transplant centers. The following proposed CoPs for approval and re-approval of transplant centers contain provisions that are specific only to kidney transplant centers (see Section II. Provisions of the Proposed Regulation for further discussion of the requirements):

- Condition of participation: Patient and living donor selection (proposed § 482.90(a)(1));
- Condition of participation: Patient and living donor management (proposed § 482.94(c)(3)); and
- Condition of participation: Additional requirements for kidney transplant centers (proposed § 482.104).

2. Extra-renal Organ Transplant Centers

Beginning in 1987, we published several notices in the **Federal Register** delineating our coverage policies regarding various organ transplants. On April 6, 1987, the Health Care Financing Administration (HCFA), now known as CMS, published a ruling (52 FR 10935) (HCFAR 87–1) announcing Medicare's national coverage policy on heart transplants. On April 12, 1991, we published a final notice (56 FR 15006) announcing Medicare's national coverage decision on liver transplants in adults. On February 2, 1995, we published a notice with comment (60 FR 6537) announcing Medicare's national coverage decision on lung transplants.

In these notices, we stated that the transplants in adults were medically reasonable and necessary and covered by Medicare under section 1862 (a)(1), 42 U.S.C. 1395y(a)(1), when performed on carefully selected patients in centers that meet certain criteria. As discussed in these notices, we based these policies on research carried out by the Battelle Human Affairs Research Center (heart) and the Public Health Service's Center for Health Care Technology (liver and lung). The specified center criteria for heart, liver, and lung transplant centers included the following:

- *Patient selection.* A center must have specific written patient selection criteria for each organ type and an implementation plan.
- *Patient management.* A center must have adequate patient management plans and protocols that include therapeutic and evaluative procedures for the waiting period, in-hospital period, and post-transplant phases of treatment.
- *Commitment.* The center must make a sufficient commitment of resources and planning of the transplant center to demonstrate the importance of the center at all levels. Indications of this commitment must be broadly evident throughout the center. The center must use a multidisciplinary team that includes representatives with expertise in the appropriate organ specialty (*e.g.*, hepatology, cardiology, or pulmonology) and the following general areas: Vascular surgery, anesthesiology, immunology, infectious diseases, pathology, radiology, nursing, blood banking, and social services.
- *Facility plans.* The center must have facility plans, commitments, and resources for a program that ensures a reasonable concentration of experience.
- *Maintenance of data.* The center must agree to maintain and, when requested, submit data to CMS.
- *Organ procurement.* The center must be located in a hospital that is a member of the OPTN as a transplant hospital, and abide by its approved rules. The center must also have an agreement with an OPO.

See Section II Provisions of the Proposed Regulations (Proposed Section 482.72) for further discussion of the OPTN rules.

- *Laboratory services.* The center must make available, either directly or under arrangements, laboratory services to meet the needs of patients.
- *Billing.* The center must agree to submit claims to Medicare only for transplants performed on individuals who have Medicare-covered conditions.
- *Experience and survival rates.* The center must demonstrate experience and success with organ transplants. The center staff must have performed a specified volume of transplants for each organ type (12 or more adult heart or liver transplants or 10 or more lung transplants) for covered conditions in each of the two preceding 12-month periods. Additionally, the center must demonstrate a minimum actuarial 1-year and 2-year survival rate. Heart transplant centers must demonstrate actuarial survival rates of 73 percent for 1 year and 65 percent for 2 years. Liver centers must demonstrate a 1-year actuarial survival rate of 77 percent and

a 2-year actuarial survival rate of 60 percent for adult patients. Lung transplant centers must demonstrate a 1-year actuarial survival rate of 69 percent and a 2-year actuarial survival rate of 62 percent.

On July 26, 2000, we issued a national coverage decision (*http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=75*), which was implemented in a program memorandum (*See* Program Memorandum AB–00–95, *http://www.cms.hhs.gov/manuals/pm_trans/2000/memos/comm_date_dsc.asp*) with an effective date of October 11, 2000. This decision announced a revision to the volume criterion for transplant centers to require 12 transplants over a 12-month period for heart and liver transplant centers, and 10 transplants over a 12-month period for lung transplant centers and to eliminate the 2-year minimum experience requirement. The memorandum was issued in response to concerns raised by hospitals that open a new transplant center staffed by an experienced team that has transferred from another Medicare-approved center. The hospitals stated that a new center, staffed with an experienced team, should receive immediate Medicare approval rather than wait at least 2 years until the center was able to demonstrate that it had performed the required volume of transplants. In response to these concerns, we solicited scientific evidence from the transplant community on the relationship between low-volume centers, transplantation team experience, and outcomes. Our analysis of the scientific literature and the information we received indicated that center volume could serve as a proxy for the 2-year minimum experience requirement. In other words, the evidence we reviewed pointed to the fact that volume is a more accurate indicator of outcome than time (see CAG–00061, *http://cms.hhs.gov/ncdr/memo.asp?id=75*, for summary of relevant clinical literature). Thus, new centers staffed with an experienced team that perform a high volume of transplants could be expected to produce satisfactory outcomes.

As of July 1, 1999, Medicare covers whole organ pancreas transplantation for diabetic patients, when it is performed simultaneously with or after a kidney transplant. (*See* sections 35–82 of Coverage Issues Manual.) Effective for services provided on or after April 1, 2001, Medicare covers isolated intestinal transplant, combined liver-intestinal transplant, and multivisceral transplant. Coverage for all three types of intestinal transplants is limited to patients who have irreversible intestinal failure and who have failed total parenteral nutrition (TPN). To be Medicare-approved, an intestinal transplant center must have an annual volume of 10 transplants with a 1-year actuarial patient survival rate of 65 percent (See Program Memorandum AB–01–58).

D. Living Donors

Since 1990, living donation has become the fastest growing source of kidneys for kidney transplants and, more recently, of livers for liver transplants. In 2001, the number of living donors exceeded the number of deceased donors for the first time. There were 12,591 organ donors in the U.S. in 2001; 6,510 were living donors and 6,081 were deceased donors. In 2003, the number of living donors continued to exceed the number of deceased donors. In 2003, there were 13,278 organ donors in the U.S.; 6,821 were living donors and 6,457 were deceased donors. Living donor transplantation provides an alternative to deceased donor transplantation for a growing number of waitlist patients. Of the 25,468 transplants performed in the U.S. in 2003, 6,811 were living donor transplants, which is a 3.0 percent increase from the 6,616 living donor transplants performed in 2002. Meanwhile, the number of deceased donor transplants rose by 2.0 percent from 18,292 in 2002 to 18,657 in 2003.

As living donor transplantation increases, there is growing concern over the safety of living donors. Most of the living donor transplant data reported are for kidney and liver transplants. Other types of living donor transplants are rare and data are scarce. For example, among the 6,811 living donor transplants performed in 2003, 6,468 were kidney transplants, 321 liver transplants, 15 lung transplants, 0 pancreas transplant, and 4 intestinal transplant. 3 kidney-pancreas transplants were performed. The risk of donor death for living kidney donors has been very low. In the 46-year history of living donor kidney transplantation, the risk of donor death is estimated to be approximately 0.03 percent.

For example, if we look at the 6,468 living donor kidney transplants performed in 2003 (out of a total of 15,138 living and deceased kidney transplants performed in the U.S. in 2003), we estimate that fewer than 2 of those transplants would result in donor death. Although there is a relatively low risk of donor death for living kidney donors, recent research seems to indicate that living kidney donation may increase the donor's morbidity. For example, a United Network for Organ Sharing (UNOS) study indicated that a total of 56 previous living donors were identified as having been listed for transplantation. It is unknown if more living kidney donors had suffered from renal failure as well (Ellison MD, McBride MA, Taranto SE, Delmonico FL, Kauffman HM. ''Living Kidney Donors in Need of Kidney Transplants: A Report From the Organ Procurement and Transplantation Network. *Transplantation,* 2002 November 15; 74(9): 1349–51). Living renal donation has long-term risks that may not be apparent in the short term, which leads us to believe that potential donors should be informed of these long-term risks.

The risk of donor death for living liver donors is higher than the risk of donor death for living kidney donors. In the 13-year history of living donor liver transplants (LDLTs), the risk of donor death has been estimated to be approximately 1 percent. Living liver donors face a higher risk of morbidity and mortality than living kidney donors due in part to complications from blood clotting, bile duct leakage, and infections. Furthermore, the rapid growth of adult LDLT as an alternative to deceased transplantation has resulted in great variation in surgical techniques, center volumes and recipient and donor selection criteria.

In addition to concerns over donor morbidity and mortality, there is also growing concern about the lack of standard guidelines governing living donor selection and post-operative care. For example, in 2002, a living liver donor death was reported in a transplant hospital in New York. The New York Department of Health launched an investigation into the donor's death and found that the donor's post-operative care was inadequate and fragmented. The New York Department of Health's investigation report concluded that inadequate staffing was a contributing factor in the donor's death (''NY Department of Health charges inadequate staffing a factor in live donor's death at Mt. Sinai Hospital,'' *Transplant News*, March 15, 2002, at 5.).

Accurate physical and psychosocial assessments of the suitability of prospective donors are imperative to reduce the likelihood of harm to healthy donors. In the absence of national guidelines for donor selection, it is difficult to ensure that living donations are performed safely. Currently, there are few worldwide registries to track living donor outcomes. The OPTN, however, gathers 1-year post-donation

follow-up data on living donors in the US.

Section 1881(d) of the Act entitles any individual who donates a kidney for transplant surgery to Medicare benefits under parts A and B with respect to such donation. Medicare does not have a national coverage determination regarding extra-renal living donor transplants. In the absence of a national coverage determination, however, Medicare contractors may make local coverage determinations either on a claim-by-claim basis or through local medical review policies. We have some concerns about the lack of standardized recipient and donor selection criteria, best practices in living donation procedures, a national outcomes database of donors' long-term follow-up and the variability in surgical expertise, volumes and center resources given the growth in living donor transplants. More systematic data collection and reporting of donor and recipient mortality and morbidity are needed to further assess the risk of death for living donors and the benefit for recipients. Generally, we believe living donation is a very promising medical practice. Therefore, in order to protect the safety of living donors and guarantee the more efficient use of human organs, we have proposed some minimal requirements for transplant centers performing living donor transplants that would apply to all Medicare-approved centers that perform living donor transplants. In accordance with our authority to establish standards necessary for the health and safety of individuals furnished services in hospitals, we believe we possess sufficient authority to prescribe rules for this practice. We invite public comments on these proposed requirements for living donor selection and living donor rights (*see* Section II. Provisions of the Proposed Regulations for a detailed discussion of these proposed requirements). We also request comments on whether we need to establish additional criteria for transplant centers performing living donor transplants.

[If you choose to comment on this issue, please include the caption ''CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANPLANT'' at the beginning of your comments.]

E. Why We Are Proposing New CoPs for Transplant Centers

Our current Medicare coverage policies for extra-renal organs are based on the ''reasonable and necessary'' provision, Section 1862(a)(1)(A) of the Act. (''[N]o payment may be made under part A or part B for any expenses incurred for items or services—(1)(A) which * * * are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'') Generally a medical procedure will be covered if its safety and efficacy have been adequately demonstrated by scientific evidence and the medical community has generally accepted the procedure. In the **Federal Register** notices announcing the Medicare coverage policies for heart, liver, and lung transplants, we stated that organ transplants in adults were reasonable and necessary when performed on carefully selected patients in facilities that meet certain criteria.

In the past decade, however, the medical community has made remarkable strides in organ transplantation, and data on successful transplant outcomes are compelling. Organ transplantation is generally very effective and successful. Patients who have received transplants benefit substantially from these life-saving procedures in terms of improved quality of life and longer lifetime. Aided by ongoing evolution in pharmacology and transplant technology, organ transplantation is no longer regarded as an experimental procedure by the medical community and most health insurance companies. Instead, transplantation has become the mainstream operation for many patients who are in the end stage of organ failure.

Furthermore, cutting-edge medical technology and pharmacology have raised graft and patient survivals significantly, such that we recognize that the survival standards that we had established previously for heart, liver, and lung centers may be too low. The national mean 1-year patient survival rates for heart, liver, and lung transplants performed in all transplant centers are much higher than the 1-year patient survival thresholds we established in our earlier national coverage decisions for Medicare approval of heart, liver, and lung transplant centers.

Furthermore, the current requirements for heart, liver, and lung centers established threshold requirements for Medicare reimbursement but do not include criteria for re-evaluating the ongoing performance of approved heart, liver and lung centers. Since organ transplantation is a medical procedure that depends completely on organs donated from an appropriate donor, any potential outcome failure should be minimized to minimize organ wastage. Ongoing evaluation of a transplant center's outcomes would serve as a valuable oversight tool for guaranteeing that donated organs are used efficiently. By establishing criteria for data submission, outcome measures, and process requirements, we can assume that Medicare-approved transplant centers would continue to provide a sufficient quality of transplantation so that organ wastage due to transplant failure would be decreased.

We believe it is important to promulgate regulations that will allow CMS to take advantage of advances in medical technology and establish standards for facilities that will ensure that Medicare beneficiaries receiving care at Medicare-approved transplant centers receive quality transplantation services. We are proposing rules that will encourage centers to seek approval to perform transplants on patients and that will include reasonable requirements necessary to produce a high probability of success. We believe these rules will lead to more efficient usage of donated organs and enhance effective administration of the Medicare program. We are proposing to codify the requirements for the approval and re-approval of transplant centers as an option for hospitals under part 482, Subpart E. These regulations would apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers. For purposes of this regulation, intestine centers are those Medicare-approved liver transplant centers that perform intestinal transplants, combined liver-intestinal transplants, and multivisceral transplants. Pancreas centers are those Medicare-approved kidney transplant centers that perform pancreas transplants, alone or subsequent to a kidney transplant, and that perform kidney-pancreas transplants.

The requirements for Medicare-approved transplant centers have been published over the years in the **Federal Register**, the Coverage Issues Manual, and 42 CFR part 405, subpart U. Locating the Medicare requirements for different organ types has proven difficult for hospitals desiring to become Medicare-approved transplant centers. Therefore, we are proposing to include the criteria for all of the organ transplant types (*i.e.*, heart, heart-lung, intestine, kidney, liver, lung, and pancreas) in the same CFR part: 42 CFR part 482. Although we received some comments during the Town Hall Meeting in December 1999 expressing the view that kidney transplant center criteria should remain with the ESRD facility conditions, we believe it will facilitate ease of reference and understanding if all the transplant center criteria are

consolidated into a specific set of hospital policies.

Entities that request approval as a Medicare transplant center must first meet all of the hospital CoPs in 42 CFR part 482; however, inclusion of the organ transplant center criteria in the hospital CoPs does not imply that every hospital must meet the criteria in order to participate in Medicare. Rather, the transplant criteria represent an optional status based on conditions that are applicable only to hospitals that choose to apply for Medicare approval as a transplant center. Each type of organ transplant center would be approved separately, so only the approval of the individual organ-specific transplant center would be threatened if it were found non-compliant with the CoPs for transplant centers. That is, the hospital would not face the automatic loss of its Medicare approval as a hospital (or the loss of Medicare approval for other transplant centers) if one transplant center in the hospital were found to be noncompliant with the CoPs for that type of transplant center.

II. Provisions of the Proposed Regulations

For the reasons discussed previously, we propose to set forth new hospital CoPs for the approval and re-approval of transplant centers at part 482, subpart E of this chapter. Following is a discussion of the specific requirements contained in the proposed conditions.

Special Requirements for Transplant Centers (Proposed Section 482.68)

The requirements for approval and re-approval of transplant centers contained in this proposed rule represent special requirements that a transplant center must meet in order to receive Medicare approval as an organ-specific transplant center. Therefore, we propose a hospital that has a Medicare provider agreement must meet the CoPs specified in § 482.70 through § 482.104 in order to be granted approval from CMS and to receive reimbursement for providing transplant services. We propose that unless we specify otherwise, the CoPs specified in § 482.70 through § 482.104 apply to all transplant centers addressed in this proposed rule (*i.e.*, heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers).

We also propose that transplant centers seeking Medicare approval meet the hospital conditions of participation specified in § 482.1 through § 482.57. In other words, if the hospital in which a transplant center operates is terminated from Medicare, the transplant center would also lose its Medicare approval. However, loss of a transplant center's approval status would not automatically lead to termination of the hospital's provider agreement.

Definitions (Proposed § 482.70)

For clarity, we propose standardizing the usage of certain terms by proposing definitions for ''transplant hospital,'' ''transplant program,'' and ''transplant center.'' Sometimes CMS has used the term ''transplant center'' interchangeably with the term ''transplant hospital'' and sometimes it has used it interchangeably with the term ''transplant program.'' We propose defining ''transplant hospital'' as a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients. A transplant hospital may have one or more types of organ transplant programs operating within the same hospital. Based on the definition of ''transplant program'' set forth at 42 CFR 121.2, we propose defining a ''transplant program'' as a component within a transplant hospital that provides transplantation of a particular organ type. Under the proposed definitions for ''transplant hospital'' and ''transplant program'', we propose to use ''transplant center'' interchangeably with ''transplant program'' in this proposed rule.

We propose to delete the definitions for ''histocompatibility testing,'' ''ESRD Network,'' ''network organization,'' organ procurement,'' ''renal transplantation center,'' ''transplantation service,'' and ''transplantation surgeon'' contained in § 405.2102. To emphasize the distinct statutory requirements that kidney transplant centers have to meet and to clarify usage of three terms in the proposed CoPs for transplant centers, we propose to retain in § 482.70 the definitions for ''ESRD,'' ''ESRD network,'' and ''network organization'' from § 405.2102.

We propose adding a definition for ''adverse event'' because we propose requiring a center to establish a written policy to address adverse events that occur during any phase of an organ transplantation case. The proposed definition for ''adverse event'' is derived from the JCAHO definition of an ''adverse event'' and provides examples of adverse events that may occur in a transplant center.

To reduce confusion, we also propose definitions for the particular types of organ transplant centers addressed in this proposed rule that perform multi-organ transplants. We propose including definitions for ''heart-lung transplant center,'' ''pancreas transplant center,'' and ''intestinal transplant center'' as they are used in this proposed rule.

These definitions, as we propose to include them, are contained in the regulatory text at proposed § 482.70.

Proposed General Requirements for Transplant Centers

Condition of Participation: OPTN Membership (Proposed section 482.72)

The OPTN was established under section 372 of the Public Health Service (PHS) Act, as enacted by the National Organ Transplant Act of 1984 (Pub. L. 98–507), and amended by Public Law 100–607 and Public Law 101–616. Section 372 of the PHS Act requires the Secretary to provide, by contract, for the establishment and operation of the OPTN to manage the national organ allocation system, to increase the supply of donated organs, and to perform related activities. Since 1986, the Health Resources and Services Administration's (HRSA) Division of Transplantation (DoT) has administered a contract with UNOS to operate the OPTN. On October 20, 1999, HRSA published regulations governing the operation of the OPTN at 42 CFR Part 121 (64 FR 56650).

The primary functions of the OPTN are (1) to ensure that critically-ill and medically-qualified patients have equitable access to organs; (2) to ensure the safe and efficient recovery and use of scarce vital organs; and (3) to collect, maintain, and track information on all transplants and transplant patients from the time of surgery until graft failure or patient death. Although the OPTN regulations referred to above include some provisions that apply to OPTN members, including transplant centers, the OPTN regulations at § 121.4 also require the OPTN to establish policies for its members in order to achieve the goals of the OPTN. As required by the OPTN regulations at § 121.4, policies are established concerning organ procurement and transplantation for OPTN members. These policies established by the OPTN are legally enforceable against OPTN members if the Secretary approves them and they are published in the **Federal Register** in accordance with § 121.4. The Secretary enforces the OPTN policies, or rules, pursuant to the procedure laid out at § 121.10. To date, no OPTN policies have been approved by the Secretary.

Until enactment of the Omnibus Budget Reconciliation Act (OBRA) of 1986 (Pub. L. 99–509), membership in the OPTN was voluntary. However, section 9318 of the OBRA of 1986 added section 1138(a)(1)(B) to the Act to require hospitals that perform organ

transplants to be members of and abide by the rules and requirements of the OPTN as a condition for participation in the Medicare and Medicaid programs. In accordance with section 1138(a)(1)(B) of the Act, the hospital condition of participation for organ, tissue, and eye procurement at § 482.45(b)(1) requires that a hospital in which organ transplants are performed must be a member of the OPTN and abide by the OPTN rules that have been approved by the Secretary. We propose that transplant centers must be located in a transplant hospital that is a member of and abides by the rules and requirements of the OPTN as set forth in § 482.45(b)(1), which are enforceable under § 121.10. We propose that no transplant hospital would be considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the proposed rule, unless the Secretary had given the OPTN formal notice that he or she approved the decision to exclude the transplant hospital from the OPTN and had notified the center in writing.

Condition of Participation: Notification to CMS (Proposed section 482.74)

The current requirements for coverage of heart, liver and lung transplants require a Medicare-approved transplant center to report immediately to CMS any events or changes that would affect its approved status. Specifically, a center is required to report to us, within a reasonable period of time, any significant decrease in its experience level (for example, volume) or survival rates, the departure of key members of the transplant team or any other major changes that could affect the performance of heart, liver or lung transplants at the facility. There are no requirements for kidney transplant centers to report significant changes to CMS. We are proposing to require each transplant center to report immediately to CMS information on any significant changes that would affect its approval, such as an unusually large number of patient deaths during or shortly after transplant that could impact the center's 1-year patient survival rates or a change in key staff members, such as the individual the transplant center designates to the OPTN as the center's ''primary transplant surgeon'' or ''primary transplant physician.'' This would be a new requirement for kidney, pancreas, heart-lung, and intestine transplant centers. We believe this requirement is necessary for all transplant centers to ensure that each transplant center maintains the resources and commitment needed to safely and efficiently perform transplants throughout its approval period.

Condition of Participation: Pediatric Transplants (Proposed Section 482.76)

Section 4009(b) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) (Pub. L. 100–203) indicates that pediatric heart transplant centers are Medicare-approved heart transplant centers if they meet certain criteria. Public Law 100–203 specified the following criteria: (1) The hospital's pediatric heart transplant center is operated jointly by the hospital and another facility that is Medicare-approved; (2) the unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and (3) the hospital demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients (See Section 35–87 of the Coverage Issues Manual). We currently use criteria for pediatric liver and lung transplant centers similar to the criteria that were specified by Congress for pediatric heart transplant centers. (See Section 35–53.1 of the Coverage Issues Manual for liver transplants and 60 FR 6537 for lung transplants.)

Since many centers that perform pediatric transplants are not jointly operated by another facility that is Medicare-approved, we propose to require all transplant centers, adult and pediatric, that wish to be reimbursed for pediatric transplants performed on Medicare beneficiaries to specifically request Medicare approval to perform pediatric transplants. We would approve and re-approve the center to perform pediatric transplants using the procedures described in proposed § 488.61. A center that wishes to be approved to perform pediatric transplants would have to meet the conditions of participation contained in § 482.68 through § 482.74 and § 482.80 through § 482.104 with respect to its pediatric patients. However, given Congress's intent that pediatric heart centers could participate in Medicare if they meet the requirements described in section 4009(b) of OBRA 1987, we are proposing to retain the statutory criteria as an option for heart transplant centers that wish to become Medicare-approved to perform pediatric heart transplants. In other words, a center that wishes to be approved to perform pediatric heart transplants may be approved by meeting the data submission, outcome, and process requirements proposed in this regulation, or the center may be approved by meeting the criteria in section 4009(b) of OBRA 1987.

Although all transplant centers that wish to be reimbursed for transplants performed on pediatric Medicare beneficiaries would have to request Medicare approval to perform pediatric transplants, we believe it is necessary to distinguish between two different types of centers that may provide pediatric transplantation services. In some centers, patients are predominantly adults (*i.e.*, 18 years or older) and only a few pediatric transplants are performed. In other centers, pediatric transplant programs are separate from the adult programs and may be operated by departments of pediatrics or children's hospitals where a majority of transplants are performed on pediatric patients (*i.e.*, patients younger than 18).

We propose that in centers where patients are predominantly (≤50 percent) adult patients, the center would need to have Medicare approval to perform both adult and pediatric transplants in order to be reimbursed for transplants performed on pediatric Medicare beneficiaries. Since few transplants are performed on children in such centers, we propose that loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, would result in loss of Medicare approval to perform pediatric transplants. However, loss of Medicare approval to perform pediatric transplants would not affect the center's Medicare approval to perform adult transplants.

Likewise, we propose that a center that predominantly (≥50 percent) provides transplantation services to pediatric patients (*i.e.*, a pediatric center) would need to have Medicare approval to perform both pediatric and adult transplants in order to be reimbursed for transplants performed on adult Medicare beneficiaries. In this case, however, loss of Medicare approval to perform adult transplants would not impact the center's Medicare approval to perform pediatric transplants while loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, would result in loss of Medicare approval to perform adult transplants. Usually, centers that predominantly serve pediatric patients will transplant only a few young adults (18 or 19 years old) who wish to maintain continuity of care but have aged beyond the pediatric patient classification. Because of the occasional adult patients being transplanted at the pediatric centers and the relatively few pediatric transplants in general, we are not requiring a minimum number of

transplants (adult or pediatric) for pediatric centers. We are requesting comments on our proposed methodology for approving and re-approving centers that perform pediatric transplants.

[If you choose to comment on this issue, please include the caption ''CENTERS PERFORMING PEDIATRIC TRANSPLANTS'' at the beginning of your comments.]

Proposed Transplant Center Data Submission and Outcome Requirements

Condition of Participation: Data Submission and Outcome Measure Requirements for Initial Approval of Transplant Centers (Proposed section 482.80)

[If you choose to comment on this section, please include the caption ''OUTCOME MEASURE REQUIREMENTS'' at the beginning of your comments.]

A. Overview

Our intent in promulgating this rule is to establish quality standards for approval and re-approval of transplant centers participating in Medicare. We intend to focus regulations on the actual care being furnished and the outcomes of that care, rather than solely on the underlying policies and procedures.

The Institute of Medicine (IOM) highlighted the importance of focusing on outcomes in its report (''Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule''), published on July 22, 1999. In its recommendation on Federal oversight, the IOM articulated its view that the Department should include greater use of patient-centered, outcome-oriented performance measures for OPOs, transplant centers, and the OPTN.

Some representatives from the transplant community that attended the CMS Town Hall Meeting held in December 1999 also voiced a similar opinion that transplant center performance should be assessed using patient-centered outcome measures. However, there was no consensus on how to design an outcome-oriented system for evaluating center performance.

We recognize the fact that transplant outcomes and practices can be assessed from multiple perspectives, and there is no one single criterion that can adequately evaluate the performance of a transplant center. Therefore, we are proposing to evaluate a center's performance by measuring a center's outcomes and experience, in combination with some specific process requirements we believe will ensure the quality of the transplant center.

In developing a proposed framework for the initial approval of transplant centers, we have included criteria of significance to an outcome-based evaluation system. We are proposing criteria for timely and complete data submission, patient survival, and graft survival.

B. Data Submission Requirements for Initial Approval of Transplant Centers

1. Current Medicare Data Submission Requirements

Under current transplant policies for heart, liver, and lung centers and the current regulations for renal transplant centers, centers applying for Medicare approval are required to supply data to CMS. As appropriate, these applicants must report every heart and liver transplant performed since 1982, every lung transplant performed since January 1, 1990, or every kidney transplant performed during the most recent year of operation and during each of the preceding 2 calendar years. The current criteria for approval of heart, liver, and lung transplant centers require centers to agree to maintain and routinely submit to CMS, in a prescribed standard format, summary data about patients selected, protocols used, and short- and long-term outcomes on Medicare and non-Medicare patients undergoing transplantation.

2. Data Collection and the OPTN

In addition to supplying transplant data to CMS, transplant centers also collect and submit transplant data to the OPTN. Under the Department's Health Information Privacy Rules at 45 CFR 164.512, which implement the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA), covered entities are permitted to use and disclose protected health information to OPOs or other organizations engaged in the procurement, banking, or transplantation of organs, eyes, or tissues from deceased donors. Therefore, data submission to the OPTN is an exception under HIPAA with respect to organ transplants. The OPTN database utilizes electronic submission, review, and modification features through a secure, encrypted web-based system. Under contract with HRSA, the OPTN develops policies concerning data submission as well as policies concerning organ procurement and transplantation.

The OPTN requires its members to submit organ-specific data electronically to the OPTN through the use of standardized forms. There are a total of 26 different organ-specific forms containing more than 3,500 data fields. Transplant centers are responsible for submitting the appropriate organ-specific forms for each center using six form types. The OPTN also specifies time frames in which each form must be submitted to the OPTN. Below is a description of the six forms for which transplant centers are responsible and the due dates established by the OPTN for each form:

- *Transplant Candidate Registration Form* includes waitlist data as well as other clinical and organ-specific information collected prior to transplant. There is a form for each organ type: Kidney-pancreas, kidney, pancreas, liver, intestine, heart, lung, and heart-lung. The OPTN requires transplant centers to submit the organ-specific Transplant Candidate Registration Form to the OPTN within 30 days of the form generation date.
- *Transplant Recipient Registration Form* includes the patient status at discharge, pre- and post-transplant clinical information, as well as treatment data. The form is generated when the patient receives a transplant and is removed from the waitlist. There is a form for each organ type: kidney-pancreas, kidney, pancreas, liver, intestine, and thoracic (*i.e.*, heart, lung, and heart-lung). The OPTN requires transplant centers to complete the organ-specific Transplant Recipient Registration Form when the transplant recipient is discharged from the hospital or six weeks following the transplant date, whichever is first. The OPTN also requires transplant centers to submit the organ-specific Transplant Recipient Registration Form to the OPTN within 60 days of the form generation date.
- *Transplant Recipient Follow-up Form* is generated six months post-transplant (excluding thoracic) and on the transplant anniversary for every living organ recipient with a functioning graft. It includes patient status, clinical, and treatment information. There is a form for each organ type: Kidney-pancreas, kidney, pancreas, liver, intestine, and thoracic. The OPTN requires transplant centers to submit the organ-specific Transplant Recipient Follow-up Form to the OPTN within 30 days of the form generation date unless the transplant recipient dies or experiences a graft failure. In such circumstances, the OPTN specifies that transplant centers are required to submit the organ-specific Transplant Recipient Follow-up Form to the OPTN within 14 days of the recipient's death or graft failure.

• *Post Transplant Malignancy Form* is generated after a malignancy has been reported on the Transplant Recipient Follow-up Form. The OPTN requires transplant centers to submit the Post Transplant Malignancy Form to the OPTN within 30 days of the form generation date.

• *Living Donor Registration Form* collects data for all living organ donors. The OPTN requires transplant centers to submit the Living Donor Registration Form to the OPTN within 30 days of the form generation date.

• *Living Donor Follow-up Form* includes patient status and clinical information collected on the living donor at intervals of six months and one year post-transplant. The OPTN requires transplant centers to submit the Living Donor Follow-up Form to the OPTN within 30 days of the form generation date.

The OPTN also includes a data submission standard that requires, among other things, 95 percent of the required forms to be completed within 90 days of their due date.

3. The Scientific Registry of Transplant Recipients (SRTR) and the Center-Specific Reports

Once the OPTN collects the required data, the SRTR, which is run by the University Renal Research Education Association (URREA) under contract with HRSA, analyzes the OPTN data and creates national and center-specific reports. Regulations at 42 CFR 121.11 require the SRTR to make center-specific information on the performance of transplant centers available over the Internet and requires the SRTR to update these data at least every 6 months. URREA updates the center-specific reports every January and July, and makes the center-specific reports available over the Internet at *http://www.ustransplant.org.*

The SRTR center-specific reports contain a variety of statistical tables based on the transplants performed at each center in the US. The center-specific reports contain information on each center's performance; including statistics on each center's waitlist activity, deceased and living donor transplant recipient characteristics and outcomes (including patient and graft survival), and donor characteristics. The SRTR also prepares national summary reports of these topics by center. Below, we provide a more detailed description of some of the statistics available in the center-specific reports.

The most important outcome for a lifesaving technology such as transplantation is whether the patient survives the procedure. Currently, the SRTR center-specific reports provide observed and expected patient survival rates for adult and pediatric patients at the 1-month, 1-year, and 3-year reporting time point for each center. For calculation of the 1-month, 1-year, and 3-year patient survival statistics, the SRTR center-specific reports use transplants that occurred during a 2.5-year interval before a report is published. In order to maximize follow-up of patients that were transplanted towards the end of the 2.5-year interval, there may be a significant lag between the time that the last transplant in the 2.5-year period occurred and the time that patient survival statistics are reported. For example, the July 2003 center-specific reports contain 1-month and 1-year patient survival statistics for abdominal transplants (for example, kidney, kidney-pancreas, intestine, liver, and pancreas transplants) that were performed at a center between January 1, 2000 and June 30, 2002 and for thoracic transplants (for example, heart, heart-lung, and lung transplants) that were performed between January 1, 2000 and June 30, 2002. In the future, the SRTR plans to calculate 1-month and 1-year survival statistics using 2.5-year cohorts for all organs. The 3-year patient survival statistics include transplants performed between January 1, 1998 and December 31, 1999. Additionally, the SRTR center-specific reports include adult patient survival rates and pediatric patient survival rates for deceased and living donor transplants.

A center's observed patient survival rate is an estimate of the fraction of patients in each cohort that would still be alive at the reporting time point had follow-up data been received up to that time. The SRTR uses the Kaplan-Meier method to calculate a center's observed patient survival rate from the OPTN follow-up data and the Social Security Death Master File (SSDMF) data. The Kaplan-Meier method is a standard statistical technique for estimating survival at the reporting time point by assuming that the failure rate would have been the same for those patients lost to follow-up as was observed for patients with complete follow-up data.

Recognizing that some patients are lost to follow-up for reasons beyond a transplant center's control, such as a patient's change of residence, change of providers, or unreported death, the SRTR began augmenting the OPTN data by tracking all transplant patients ''lost to follow-up'' through the SSDMF. Although there are some flaws in the SSDMF data, it has enhanced the SRTR's ability to determine if patients ''lost to follow-up'' had died or were still thought to be alive on a certain date. In addition to enhancing the accuracy of the SRTR's center-specific reports, URREA has determined that the additional data obtained from the SSDMF seems to increase the reported survival rates of some centers.

A center's expected patient survival rate is a risk-adjusted statistic that provides an estimate of the fraction of patients who would be expected to be alive at each reported time point based on the national experience for similar patients. The SRTR uses the Cox proportional hazards regression model to calculate each center's expected patient survival rate.

The Cox model is a statistical modeling technique that is widely used in the analysis of survival data. The Cox model is flexible in the types of data, event rate patterns, and covariates it can handle. It can model dependence of event rates on patient and donor characteristics in a variety of ways including time dependent proportional hazards (covariates), which are extremely useful for modeling the effect of current patient status on mortality and for modeling both short term and long term covariates effects on event rates. Information about the Cox model can be found on the Internet. For example, background on the Cox model can be found at *http://members.aol.com/johnp71/prophaz.html.*

The Cox model is designed to evaluate the outcomes among the recipients at one center, compared to what would be expected, had those same patients received a transplant at an ''average'' center. One of the most important features of the Cox model is the identification of the adjustment factors that could affect transplant outcomes. These factors are chosen using clinical input supported by statistical analyses. The clinical input comes from the constant review of SRTR models by experts on the OPTN committees and the Secretary's Advisory Committee on Organ Transplantation (ACOT). The Secretary established the ACOT to enhance organ donation, ensure the system of organ transplantation is grounded in the best available medical science, ensure the public that the system is as effective and equitable as possible, and thereby increase public confidence in the integrity and effectiveness of the transplantation system. Some non-statistically significant factors are also included in the Cox models used to calculate expected patient survival in order to improve validity and public acceptance of the models.

Historically, there have been more than 100 models fit for each center-specific report release (*e.g.*, models by organ, by age group, by living/deceased donor, by follow-up time period, by graft/patient survival). Currently, the models used to calculate 1-month and 1-year patient survival are based on the same cohort of patients. The SRTR plans to begin to use a single model to calculate survival, as this would allow for more stable estimation of factors for the 1-month results, which currently are based on relatively few events. This will assure consistency in the expected values for the overall transplant population and the subpopulations of living and deceased donor recipients.

The specific risk adjustment factors that affect transplant outcomes identified in the Cox model and their weights are subject to change with each updated analysis. Semi-annually (every January and July), the SRTR assesses the goodness of fit and stability of a survival model using the index of concordance. The index of concordance is a measure of a model's ability to fit the mortality outcomes for each patient. In order to assess the stability of the models, for each center-specific report release, the models will be fit using the same list of covariates to a series of successive cohorts of transplant recipients. In addition, the values of the coefficients will be reported for each of the models while outcomes are evaluated relative to the norm, or the ''average.'' Significant changes in the index of concordance and the coefficients over a period of time will help to identify the factors that require closer evaluation in order to be sure that the models are as up to date as possible.

In the future, the SRTR plans to complete a table for each of the center-specific report post-transplant models. The table will include the index of concordance, the coefficients, and p-values for the coefficients when the model is fit for transplants during the 2.5-year cohort used for the current center-specific report release as well as that for the two previous releases. This table will be posted publicly on the SRTR Web site (*http://www.ustransplant.org*) at the time of the preview site, which is approximately 1 month before the center-specific report public release date. It is intended to allow users to assess the stability of the models. If the fit of the models or the coefficients of the factors change markedly, one would be careful to evaluate the models to be sure that they are as up to date as possible. If the fit and coefficients do not change markedly, one could be assured that the models are stable.

For purposes of example, the Cox models used in the July 2004 center-specific reports to calculate expected 1-year patient survival rates for deceased donor adult transplants contained the following factors. (Analytic Conventions—Guide to the Center-Specific Reports, *http://www.ustransplant.org/programs-report.html*). Factors for kidney transplants included: diagnosis, donor age, donor history of hypertension, donor meets expanded donor criteria for deceased kidney, donor race, donor serum creatinine, donor cause of death, human lymphocyte antigen (HLA) mismatch, peak panel reactive antibody (PRA), recipient age, recipient ethnicity, recipient medical condition, recipient race, and year of ESRD treatment. Factors for liver transplants included: diagnosis, ABO (*i.e.*, blood types A, B, AB, and O) compatibility, donor Hispanic/Latino, donor age, donor and recipient in the same region but not the same OPO, donor and recipient not in same region or OPO, donor race, donor cause of death, non heart beating donor, recipient portal vein thrombosis, recipient age, recipient any previous transfusions, recipient ascites, recipient creatinine, recipient ethnicity, recipient height, recipient incidental tumor found at time of transplant, recipient insulin dependent diabetes, recipient medical condition, recipient on life support, recipient previous abdominal surgery, recipient race, and split or partial liver. Factors for heart transplants included: diagnosis, donor age, donor cause of death, ischemia time, recipient creatinine, recipient height, recipient medical condition, recipient on extracorporeal membrane oxygenation (ECMO), and recipient on ventilator. Factors for lung transplants included: cardiac index, diagnosis group B, diagnosis group C, diagnosis group D, diagnosis, donor age, donor body surface area, donor history of diabetes, donor race, donor cause of death, percent predicted forced vital capacity (FVC), ischemia time, New York Heart Association (NYHA) class, oxygen required at rest, recipient age, recipient creatinine, recipient female, recipient on ventilator, recipient race, and pulmonary artery (PA) hemodynamics mean by diagnosis interaction.

As in patient survival, the SRTR also calculates observed and expected 1-month, 1-year and 3-year graft survival statistics. Using the Kaplan-Meier method, the SRTR calculates observed graft survival rates for each of the reporting time points (*i.e.*, 1-month, 1-year, and 3-year) from OPTN and SSDMF data. Cox models are used to calculate expected graft survival statistics for each of the reporting time points. The factors predictive of graft survival models are generally similar to those predictive of patient survival models and generally include an indicator for whether or not this was the first transplant of this type. Again, 1-month, 1-year, and 3-year graft survival statistics in the center-specific reports are stratified by age (*i.e.* adult or pediatric) and by donor type (*i.e.* deceased or living) and are calculated using only transplants that occurred during a 2.5-year interval before a report is published.

4. Proposed Data Submission Requirements

Since the SRTR center-specific reports contain a wealth of information about transplant center outcomes and the SRTR prepares its analytical reports from the data that transplant centers are already self-reporting to the OPTN, we propose that the SRTR's center-specific reports could form the foundation for our outcome evaluation system. However, we need to be certain of the completeness of the data used to evaluate each center's outcomes.

In July 2001, an article that appeared in the *Milwaukee Journal Sentinel* (''Transplant Rate Reports Don't Tell Whole Story,'' *http://www.jsonline.com/alive/column/jul01/marccol30072701.asp*, July 27, 2001) questioned the data used by the SRTR to generate and publish the center-specific reports. The article charged that some centers were getting away with reporting less than half of follow-up data required by the OPTN. Incomplete data can be attributed to several factors, including lost to follow-up. However, the article also alleged that some centers were purposely submitting incomplete data to skew their survival results. In order to ensure that the data used by the SRTR for analysis and compilation of the national and center-specific reports are comprehensive and accurate, we believe that it is important that we establish requirements for timely and complete reporting of data to the OPTN.

As discussed earlier, the OPTN includes a data submission standard that requires, among other things, 95 percent of the required forms to be completed within 90 days of their due date. We propose a similar data submission requirement. We propose, at § 482.80(a) that no later than 90 days after the due date established by the OPTN, heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers must submit to the OPTN at least 95 percent of required data submissions on all transplants

(deceased and living donor) performed at the center. We believe it is important to maintain this 90-day grace period to ensure that transplant data collection and compilation are as complete and accurate as possible.

We propose that required data submissions include, but not be limited to, the submission of the appropriate organ-specific OPTN forms for transplant candidate registration, transplant recipient registration, and recipient follow-up. Requiring timely and complete submission of data will ensure up-to-date and meaningful data.

C. Outcome Measure Requirements for Initial Approval of Transplant Centers

1. Current Medicare Outcome Measure Requirements

Under the current transplant policies, transplant centers applying for Medicare approval of a heart, liver or lung transplant center are required to report their 1-year and 2-year actuarial (unadjusted) patient survival rates using the modified Kaplan-Meier method. The modified Kaplan-Meier method estimates survival at the reporting time point by treating those patients lost to follow-up as dead on the day following the last ascertained survival.

The current actuarial survival standards for heart transplants were developed in 1986. According to those standards, a center is required to demonstrate an actuarial survival rate of 73 percent for 1 year and 65 percent for 2 years for patients who have had heart transplants since January 1, 1982 at that center. Current criteria for approval as a liver transplant center were developed in 1991 and require an actuarial survival rate of 77 percent for 1 year and 60 percent for 2 years for the time period the center is using to calculate survival. The criteria for lung transplants were published in our February 1995 notice of Medicare policy for lung transplants. The criteria require centers to maintain a 1-year actuarial survival rate of 69 percent and a 2-year actuarial survival rate of 62 percent for all transplant cases occurring on or after January 1, 1990.

The Medicare National Coverage Decision that we issued in October 2000 requires intestinal centers to have a 1-year actuarial survival rate of 65 percent for intestinal and multivisceral transplants. The required intestinal threshold is based on a weighted average of the national 1-year patient survival rates for small bowel transplantation, small bowel/liver transplantation, and multivisceral transplantation data from the literature reports on the international intestinal transplant registry. There are no survival standards in place for kidney, pancreas, and heart-lung transplant centers for Medicare approval.

2. Appropriateness of Current Survival Criteria

At the time the survival criteria for heart, liver and lung transplants were developed, organ transplants were largely viewed as experimental procedures and the survival criteria were designed to be high enough to ensure that Medicare-approved transplant centers were high-quality institutions but low enough to ensure that centers did not exclude high-risk patients. Aided by remarkable advances in medicine and cutting-edge technology, survival rates for heart, liver, and lung transplant patients have steadily increased since our criteria were established. For example, according to the 2003 OPTN/SRTR Annual Report, the unadjusted 1-year patient survival figures for transplants performed between 2000–2001 for deceased donor heart, liver, and lung transplantation were 86 percent, 86 percent, and 78 percent, respectively. The recent national 1-year patient survival rates are considerably higher than the corresponding Medicare 1-year patient survival standards of 73 percent for heart, 77 percent for deceased donor liver, and 69 percent for lung transplantation. It seems clear that the Medicare survival criteria currently used for Medicare approval of heart, liver, and lung centers would not be appropriate under an outcome-oriented set of standards.

We believe it is necessary for us to establish outcome measure requirements for transplant centers to protect patient safety and, given the scarcity of donor organs, to ensure that donor organs, once recovered, are transplanted effectively and are not wasted. In an effort to assure that transplant centers furnish transplantation services efficiently, we believe we need to establish a system for approval and re-approval of transplant centers that focuses on a center's outcomes. A center's outcomes serve as indicators of the center's ability to furnish transplantation services successfully. Since we are proposing a system that focuses heavily on outcomes, it is critical that the outcome standards reflect current conditions. Consequently, we are proposing significant changes in the standards that would be applicable to Medicare approval.

Moreover, we believe our responsibility to ensure that transplantation services are furnished safely and efficiently is no less important to those beneficiaries in need of kidney transplants than those in need of heart, liver, or lung transplants. Therefore, we are proposing to develop survival criteria for kidney transplant centers.

3. Proposed Outcome Measure Requirements for Heart, Kidney, Liver, and Lung Centers

It has been widely acknowledged by the transplant community that a transplant center's performance should be measured on the basis of its outcomes. However, there is no consensus on how to develop an outcome-oriented evaluation system. In developing an outcome-oriented system for evaluating center performance, some issues we considered are what types of measures should be used, how many measures to include, and whether to include both short and long-term outcomes.

The transplant community considers post-transplant outcomes, such as patient and graft survival, to be the ''gold standard'' for evaluating a transplant center's performance. While post-transplant outcomes, which measure the outcomes of transplant recipients, are widely accepted as meaningful measures of transplant center performance, organ transplantation is both a short and long-term experience.

We currently evaluate a center's performance on the basis of a single outcome measure, patient survival. For the purposes of this proposed rule we considered continuing to evaluate a center's performance on the basis of a single outcome measure. However, this approach could encourage centers to neglect other outcomes. For example, a kidney center might focus its efforts on ensuring that a kidney recipient survives to the detriment of the survival of the graft, since dialysis provides an alternative to death for kidney recipients with a failed graft.

Additionally, we are concerned that use of patient survival rates alone would not paint a complete picture of the quality of transplants performed at a center. While patient survival rates measure patient mortality, patient survival rates do not measure patient morbidity or the success of the actual transplantation procedure. Therefore, we are not proposing to limit outcome criteria for initial approval to patient survival; we are proposing a graft survival criterion as well.

We do not propose to use graft survival exclusively because patient survival is also an important measure for assessing a transplant center's quality. For example, if a transplant

center lost grafts only due to patient deaths, its outcomes may not be poor with respect to graft survival. However, since patient deaths are supposed to occur less frequently than graft loss due to re-transplants and dialysis, this transplant center may have a significantly lower than expected patient survival.

Therefore, we are proposing to use both graft and patient survival as outcome measures that would portray a center's actual performance more accurately. The proposed outcome measure requirements, like the other proposed requirements for initial approval, serve as one of several requirements that transplant centers seeking initial approval would have to meet in order to begin furnishing transplantation services that are covered by Medicare.

We also considered looking at both short-term and long-term outcomes, such as the 2-year statistics we currently require. However, we realize that long-term outcomes are more susceptible to exogenous factors not directly related to the transplantation procedure. After careful analysis of these issues, we propose using 1-year patient survival and 1-year graft survival (and in certain circumstances, 1-month patient survival and 1-month graft survival in lieu of 1-year patient survival and 1-year graft survival) as outcome measures for initial approval. We propose to require centers to meet both the 1-year patient survival and 1-year graft survival requirements separately. We propose to assess a transplant center's 1-year patient and graft survival by comparing a transplant center's expected 1-year patient and graft survival rate to its observed 1-year patient and graft survival rate for all transplants performed in the center, including living donor transplants if applicable. We propose to review a center's observed patient and graft survival against its expected patient and graft survival using a methodology that was developed by the SRTR and used by the OPTN. (This methodology, including its development, is discussed in detail below.) We propose to review a center's outcomes using the patient and graft survival data contained in the most recent SRTR center-specific report.

We also propose to review adult and pediatric outcomes separately if a center other than a lung transplant center requests Medicare approval to perform pediatric transplants. For most organ types, the SRTR has developed separate Cox models for calculating expected patient and graft survival statistics for adult (18 and older) and pediatric (younger than 18) patients. For lung transplants, however, the SRTR stratifies recipient outcomes using other categories—(1) patients that are 12 and older or (2) patients that are less than 12. Since most lung transplants performed on pediatric patients, which is traditionally defined as patients that are younger than 18 years old, are performed on older children, we propose to use the 1-year patient survival data on patients who are at least 12 years old to assess both adult and pediatric outcomes.

a. Proposed Outcome Evaluation Methodology

Some of the attendees in the CMS Town Hall Meeting expressed the view that transplant centers should be evaluated on the basis of risk-adjusted outcomes because risk adjustment can reduce the impact of patients' diverse risk factors on survival rates. We agree that risk adjustment addresses the potential to inadvertently penalize centers for transplanting high-risk patients or using organs from extended criteria donors. We believe risk adjustment can level the playing field for all transplant centers. As such, we propose an evaluation system that relies on the SRTR's risk-adjusted data.

The SRTR methodology, which was adopted by the OPTN's Board of Directors in June 2003, was designed to update deficiencies in prior OPTN methods. A discussion of prior methods used by the OPTN is available in the OPTN Proposal Archive, March 14, 2003–32 Proposals (Proposed Modifications to OPTN/UNOS Bylaw Appendix B (Criteria for Institutional Membership), Section III (Transplant Programs) at *http://www.optn.org/policiesAndBylaws/publicComment/proposalsArchive.asp*. The current SRTR method, which is being proposed for use by CMS, uses a three-pronged approach that takes into consideration (1) statistical certainty; (2) the value of the finding for allocating resources to perform on-site surveys; and (3) the need for taking action. This three-pronged approach provided the OPTN's Membership and Professional Standards Committee (MPSC) with a balanced tool for assessing transplant center performance without creating excessive demand on the resources of the MPSC.

Specifically, the SRTR methodology compares observed outcomes to expected outcomes using three tests: (1) The p-value to test for statistical significance, (2) the number of observed events (*i.e.*, patient deaths or graft failures) minus the number of expected events (O − E), and (3) the number of observed events divided by the number of expected events (O/E). When a transplant center crosses over the thresholds for all three tests, it is identified for further review by the OPTN.

The first prong of the three-pronged approach of the SRTR methodology is statistical certainty, which is based on assessing whether the difference between the observed number of deaths or graft failures is statistically significantly more than the expected number. Statistical tests often use p-values to distinguish whether chance can or cannot be ruled out or chance is a likely or unlikely explanation for the differences documented between two observations. The p-value measures the statistical significance (or evidence) for testing a hypothesis. Usually, this hypothesis is either that two numbers are equal to each other or that a number is different from zero. A p-value of less than 0.5 (indicating that there is less than a 5 percent chance that any observed difference offered by random chance alone) is often considered ''statistically significant''. Consequently, the p-value helps to identify centers where chance is an unlikely explanation for the differences between the center's observed events and its expected events.

A low p-value generally indicates that chance is an unlikely explanation for the differences between the actual and expected outcomes. The MPSC determined that a p-value less than 0.05 would be adequate to assure the statistical certainty of the difference between the observed and expected number of deaths or graft failures.

The second prong of the three-pronged approach of the SRTR methodology is the value of the finding for allocating resources to perform on-site surveys. The number of observed events minus the number of expected events (that is, the number of patient deaths or graft failures a transplant center would expect to have based on its patient population) helps to identify centers with relatively large numbers of unexpected events. The OPTN uses the results of this test to determine how to allocate its limited resources available for the review of centers. This avoids allocation of resources to centers with only a small fraction of unexpected deaths. The SRTR proposed a threshold value for each test. The MPSC determined that the number ''3'' (that is, 3 more patient deaths or graft failures than expected) would be adequate to assure that there was meaningful clinical information to assess for deficiencies in a transplant center (O − E>3). Few smaller centers are expected to show statistical significance (*i.e.*, show a p-value <0.05) because, from a statistical perspective, it hard to rule out chance when working with

small numbers. Therefore, one could expect that fewer small centers than large centers potentially would be identified using the SRTR methodology.

The OPTN MPSC recognized that it would need to be able to appropriately flag smaller cohorts, especially since the center-specific reports separate adult and pediatric transplants. As such, in 2001, the SRTR presented some analyses that would help the OPTN MPSC decide upon the minimum number of transplants needed in order for the SRTR methodology to flag smaller cohorts. Transplant centers that performed fewer transplants than this minimum number would not be reviewed using the SRTR methodology.

Although a single death has a much greater impact on a center's patient survival rate in a smaller center than in a larger center, the OPTN MPSC felt that the percentage difference when working with smaller cohorts was less useful from a clinical perspective because of the smaller numbers. For example, a transplant center that performs 10 transplants and loses 1 graft has a 90 percent survival rate whereas a center that performs 11 transplants and loses 2 grafts has an 82 percent survival rate. Although the difference between 90 percent and 82 percent may appear to be significant, when only 10 transplants have been performed, the absolute difference between the loss of 1 graft and 2 grafts is small. The MPSC felt that this type of difference was not sufficient to distinguish small cohorts. Therefore, the MPSC asked the SRTR to help them determine the minimum number of transplants required for the SRTR methodology to flag a transplant center and to have that ''flag'' be clinically appropriate.

In deciding upon the minimum number of transplants required for use of the SRTR methodology, the OPTN recognized that small transplant centers had to have a minimum excess of graft failures/deaths before there was adequate clinical information to evaluate for deficiencies in the transplant center. Since the minimum number of excess graft failures/deaths was determined to be 3, a transplant center would have to perform at least 4 transplants in order to have an excess of 3 deaths. However, performing 4 transplants and having a 100% graft failure/death rate was not clinically acceptable. Therefore, the SRTR developed a scenario in which a transplant center's expected graft failure/mortality rate was 10 percent, but its actual graft failure/mortality rate was 50 percent. Using this scenario, the SRTR methodology could flag cohorts as small as 8 transplants. Based on this finding, the OPTN MPSC decided to use the SRTR methodology on cohorts (adult or pediatric) of at least 9 transplants. As the number of transplants increase, the clinical concordance of observed and expected mortality rates should also increase.

The third prong of the approach of the SRTR methodology is the need for taking action. The MPSC determined that it would need to take action when it determined that the observed number of deaths or graft failures was 50 percent more than expected (O/E>1.5).

We applaud the SRTR's effort to strive for better ways to identify under-performing transplant centers. We have carefully reviewed and evaluated the SRTR's methodology for flagging under-performing transplant centers. We believe the SRTR approach to handling small centers is reasonable. To address concerns that the methodology could be perceived as being more lenient towards smaller centers, we analyzed transplant center data from the most recent SRTR center-specific report and found that it flagged centers of all size ranges. Of the 72 small centers (9–25 transplants), 15% were flagged.

ADULT PROGRAMS FLAGGED BASED ON CENTER SIZE

Center size	Number of programs (1)	Number of programs flagged (patient/graft/both) (2)	Flagged/program (2)/(1)
<9	71	0 (0.0%)	0%
9–25	72	11 (20.4%)	15.3%
26–50	98	11 (20.4%)	11.2%
51–100	121	13 (24.1%)	10.7%
101–200	111	15 (27.8%)	13.5%
201–500	60	3 (5.6%)	5.0%
>500	8	1 (1.9%)	12.5%
Total	541	54 (100.0%)	

We believe that the analyses we conducted shows that the p-value test performs very well for centers with at least 9 transplants. Given the fact that an adult center has to have performed 9 transplants in order to enable the SRTR methodology to capture differences during the 2.5 year cohort period, we believe the SRTR methodology can maintain a delicate balance between able to identify the outliers in both large and small centers. We are requesting comments on the appropriateness of proposing this approach.

We propose adapting the general framework of the SRTR methodology to assess a heart, liver, lung, or kidney transplant center's outcomes for our use. That is, we propose that if a transplant center's observed 1-year patient survival rate and 1-year graft survival rate is lower than the expected 1-year patient survival rate and 1-year graft survival rate, respectively, we would use the three SRTR tests (p-value, O − E, and O/E) to determine whether a center's observed survival rates were unacceptably low and whether thus the center would require CMS follow up.

For each of the outcome measures we proposed for initial approval of heart, liver, lung, and kidney centers, we propose establishing minimum thresholds for the p-value, O − E, and O/E tests. One of the primary concerns expressed by beneficiaries at our Town Hall Meeting was access to their choice of transplant centers. Therefore, we want to establish a mechanism whereby all transplant centers that perform at or near their expected outcomes are able to obtain initial Medicare approval for transplantation. We recognize that the threshold we establish for each test would affect the quality of care, number and location of centers, and access to centers. It is our goal to establish thresholds to ensure access while ensuring that Medicare beneficiaries receive high quality organ transplantation services. After careful evaluation of SRTR's analysis and OPTN's reasoning, we propose to adopt

thresholds that mirror those adopted by the OPTN.

Specifically, for each outcome measure, we propose considering the center's patient and graft survival rate to be acceptable as long as the center's observed patient and graft survival rate is higher than the center's expected patient and graft survival rate. If a center's observed patient and graft survival is lower than its expected patient or graft survival, we would still consider the center's patient and graft survival rate to be acceptable, unless all three of the following thresholds are crossed over:

- The one-sided p-value is less than 0.05;
- The number of observed events minus the number of expected events (O − E) is greater than 3; and
- The number of observed events divided by the number of expected events (O/E) is greater than 1.5.

Our justification for these thresholds is the same as that of the OPTN when it adopted the thresholds in June 2003. A one-sided p-value less than 0.05 can loosely be interpreted to mean that there is a 95 percent probability that the difference between a center's observed patient or graft survival rate cannot be explained by random fluctuations. Therefore, we believe that establishing the threshold for the p-value at 0.05 provides us with reasonable assurance that a transplant center's observed patient or graft survival rate truly cannot be attributed to external factors that may also influence patient or graft survival, as opposed to being the result of a random fluctuation (*i.e.* the difference between the observed and expected is statistically significant). A difference between the observed number of events (*i.e.*, patient deaths or graft failures) and the number of expected events that is greater than 3 indicates that 3 or more of the observed events were unexpected. In establishing the threshold for the O − E test at 3, our goal was to strike a balance between establishing a threshold that is high enough to avoid identifying centers where the absolute number of unexpected events is very small and establishing a threshold that is low enough to reflect that a non-trivial number of patients were affected. When the quotient of the number of observed events divided by the number of expected events is greater than 1.5, this indicates that a substantial fraction (more than 50 percent) of the observed events were unexpected. Therefore, the proposed thresholds for the O − E and O/E tests help to identify centers in which a relatively large portion of the center's transplants resulted in an unexpected adverse outcome (*i.e.*, patient death or graft failure).

For each outcome measure, we propose that only when a heart, liver, lung, or kidney center crosses over the thresholds established for all three tests, would we consider the center not to be in compliance with the requirements for that particular outcome measure. For example, we would consider a center that demonstrates a p-value of 1.00, O − E of 5.0, and O/E of 2.0 based on the 1-year patient survival data contained in the most recent SRTR center-specific report to meet the patient survival requirement because one of the three thresholds (that for the p-value test) was not crossed over. On the other hand, a center that demonstrates a p-value of 0.01, O − E of 5.0, and O/E of 1.9 for its patient survival data would cross over the thresholds for all three tests; therefore, we would not consider the patient survival requirement to be met.

Transplant centers would have to meet the requirements for each of the outcome measures (*i.e.,* patient survival and graft survival) separately. In other words, a center that meets the requirements for patient survival but not for 1-year graft survival would not meet the proposed outcome measure requirements. By considering centers whose observed outcomes are lower than their expected outcomes to be acceptable unless they cross over the thresholds for all three tests, we believe that we can be reasonably assured that any center identified using this methodology will have both a statistically significant and non-trivial number of unexpected deaths or graft failures. Centers in which the number of unexpected events is relatively large but not statistically significant or in which the number of unexpected events is statistically significant but relatively small would not be inadvertently penalized under this proposed methodology.

We are proposing that an adult transplant center requesting Medicare approval would have to have 1-year patient and 1-year graft survival follow-up data on at least 9 transplants of the appropriate organ type during the 2.5-year period reported in the most recent center-specific report. In other words, centers that perform fewer than 9 transplants generally would not be eligible for Medicare approval under our proposal. We are asking for comments as whether requiring the minimum number of 9 transplants during the 2.5-year period is acceptable for this application of the SRTR methodology.

CMS is cognizant that requiring a minimum number of transplants may appear to limit access to transplantation for Medicare beneficiaries. However, given that the proposed minimum number of transplants of 9 is lower than the current Medicare requirements (12 transplants over a 12-month period for heart and liver transplant centers, and 10 transplants over a 12-month period for lung and intestinal transplant centers), we do not believe this requirement would lessen current access to transplant centers. As stated earlier, our analysis of the most recent SRTR center-specific reports indicates that approximately 71 adult transplant centers performed fewer than 9 transplants in the most recent 2.5-year period. It appears that the majority of the smaller cohorts involved pediatric cases, transplant centers at children's hospitals, or centers in transition. After careful analyses, we found that 45 of those centers were the adult component of a pediatric center, which does not have to meet the proposed volume requirement. Of the remaining 26 centers, only 11 are currently active according to the records of the OPTN. Of those 11 centers, there are 5 heart centers, 1 kidney center, 2 liver centers and 3 lung centers. Also, four centers have 7–8 transplants (and could easily reach 9 transplants); 2 centers are affiliated with a large transplant center; one center recently opened; and 2 centers are located in cities with a nearby transplant center.

OPTN requirements are similar to those we propose. The OPTN currently requires that heart, kidney and liver transplant centers perform a minimum of one transplant every 3 months, which equals approximately 9–10 transplants over the course of 2.5 years. Although lung transplant programs are required to perform a transplant only once every 6 months, there were only 3 lung centers that did not perform at least 9 transplants.

Given the very specialized care that needs to be provided to children, as well as the relatively few children who are Medicare beneficiaries, we did not want to restrict access to this group by setting a volume threshold that was inappropriately high. Although we have stated we would review pediatric outcomes separately if a transplant center requests Medicare approval to perform pediatric transplants, we propose not to require such centers to perform a minimum number of pediatric transplants prior to their request for approval. Most centers that would request Medicare approval to perform pediatric outcomes are likely to perform only 2 or 3 transplants per year. Analyses conducted by HRSA's DoT staff indicate that a minimum volume requirement that would still allow the

SRTR's methodology to flag poor-performing centers would preclude most children's hospitals from being able to request Medicare approval. The OPTN, also recognizing the infrequency of pediatric transplantation, requires that only one transplant per year be performed to demonstrate that the pediatric center is functionally active. We request comments on this proposal.

We recognize that there may be some concerns related to our proposed minimum number criterion because the current Medicare volume standards for heart, liver, lung, and intestinal centers are higher. Medicare currently requires heart and liver transplant centers to perform 12 transplants over a 12-month period, and lung and intestinal transplant centers to perform 10 transplants over a 12-month period. Historically, we have used volume as a proxy for outcome. Since we now have risk-adjusted outcome measures, we believe it would be insufficient to propose a volume standard that would be viewed as arbitrary or unscientific. Instead, our volume requirement should only reflect the minimum number of transplants needed for the SRTR to be able to flag a poor-performing center, that is, 9 transplants performed during the reporting period.

If a heart center is requesting Medicare approval in December 2004, we would rely on the 1-year patient and graft survival data contained in the July 2004 SRTR center-specific report. Since the July 2004 report contains 1-year patient and graft survival data on transplants performed between January 1, 2001 and December 31, 2002, we would expect that the July 2004 center-specific report include 1-year patient and graft survival information on at least 9 heart transplants that were performed between January 1, 2001 and December 31, 2002. Meanwhile, a kidney transplant center that requests Medicare approval in December 2004 would be expected to have 1-year patient and graft survival follow-up information on at least 9 kidney transplants that were performed between January 1, 2001 and June 30, 2003, since the SRTR used a 2.5-year cohort in the July 2004 center-specific report to report patient and graft survival statistics for abdominal organs.

This lower volume criterion may also raise the concern that a center could perform 9 transplants quickly and then not perform a transplant for 12 months and yet become or remain Medicare approved. However, we believe this scenario is unlikely to occur because of additional oversight provided through the OPTN. In 1996, the MPSC of the OPTN proposed changes to the bylaws that would define a functionally inactive transplant center's responsibility to patients on the waiting list. In order to identify such centers, the MPSC set forth criteria that would trigger further investigation of transplant center functional inactivity. Initially, the MPSC considered a transplant center to be functionally inactive if it did not perform a transplant within a 3-month period. As the MPSC has gained greater understanding of the impact of the organ procurement and allocation process on a center's ability to perform transplants, it has revised the initial criteria for determining whether a center is functionally active: for heart, liver and kidney centers—a transplant every 3 months; for lung centers—a transplant every 6 months; for children's hospitals—a transplant once a year. In addition to these frequency standards, the MPSC also reviews organ offers and turndowns at centers that have not performed a transplant recently to determine whether the reason for inactivity is due to lack of suitable organ offers or inadequate resources at the transplant center. If the OPTN determines that a transplant center is functionally inactive, the transplant center is no longer eligible to receive organs for transplantation, and therefore, can no longer perform transplants. These OPTN reviews offer additional oversight to assure the public and Medicare that the organ transplant centers are truly functionally active at the time of Medicare approval and re-approval. We request comments on our proposal to focus more heavily on a center's outcomes by eliminating volume as a separate standard and integrating volume into our outcomes assessment.

b. Evaluation of Alternatives to the SRTR Methodology

Based on our analysis of the July 2004 SRTR center-specific reports, we believe that a majority of the heart, kidney, liver, and lung centers would be able to meet the proposed 1-year patient and 1-year graft survival requirements. Using data from the July 2004 SRTR center-specific reports, approximately 10.0 percent of all heart, kidney, liver, and lung centers that perform adult transplants have observed outcomes that are lower than their expected outcomes and cross over the proposed thresholds for the three tests in terms of both 1-year patient survival and 1-year graft survival. In other words, if all heart, kidney, liver, and lung centers that perform adult transplants were to seek initial Medicare approval simultaneously, approximately 10.0 percent of the 541 heart, kidney, liver, and lung centers that perform adult transplants would not be able to meet the proposed outcome measure requirements. Also, approximately 1.9 percent of the 309 heart, liver, lung, and kidney centers that perform pediatric transplants have observed outcomes that are lower than their expected outcomes and meet the proposed thresholds for all three tests. We invite comments on the proposed outcome measures and their thresholds. We specifically solicit data and evidence that may support alternative thresholds, especially thresholds that may be specific to a particular organ transplant type.

We also welcome comments on the methodology itself. We understand that the OPTN continuously reviews this methodology and may make modifications to the methodology or the thresholds for the three tests in the future. In the event that the OPTN decides to modify the methodology or any of the thresholds currently used, we would consider adopting the modified methodology or thresholds through notice and comment rulemaking.

In addition, we explored two options for applying the SRTR methodology. We would like to take this opportunity to welcome comments on these other options as well. In one option, a heart, kidney, liver, or lung center whose observed outcomes are lower than its expected outcomes would be considered to have unacceptable outcomes if it met the proposed thresholds for just two of the three tests (hereafter referred to as option 1. When we analyzed the data in the July 2004 SRTR center-specific reports, we discovered that option 1 would identify approximately 15.7 percent of the heart, kidney, liver, and lung centers that perform adult transplants and 4.2 percent of the heart, kidney, liver, and lung centers that perform pediatric transplants.

A second option consists of considering a center's outcomes to be unacceptable if its observed outcomes are lower than its expected outcomes and the center met the proposed threshold for just one of the three tests (hereafter referred to as option 2. If option 2 were selected, approximately 41.6 percent of the heart, kidney, liver, and lung centers that perform adult transplants would fail to meet the proposed 1-year patient survival and 1-year graft survival requirements and approximately 67.0 percent of the heart, kidney, liver, and lung centers that perform pediatric transplants would fail to meet the proposed 1-year patient survival and 1-year graft survival requirements.

Considering a transplant center's outcomes to be unacceptable when the center's observed outcomes are lower than its expected outcomes and the center crosses over the proposed threshold for just one or two of the three tests is more stringent than our proposal. However, we are concerned that under this option, we would be conducting inspections on centers where the differences between the observed and expected events are relatively large but not statistically significant, thus diverting resources that should be expended surveying centers where the differences between the observed and expected events are both large and statistically significant. Therefore, we are proposing to consider a center's outcomes to be unacceptable only when a center's observed outcomes are lower than its expected outcomes and the center crosses over the proposed thresholds for all three tests. We are inviting comments on the merits of our proposed approach.

For comparison, we have summarized the results of our analysis of the effects of our proposal as well as options 1 and 2 in the table below. We used data from the July 2004 center-specific reports to perform this analysis. We did not, however, screen out centers that performed fewer than 9 adult transplants when we conducted this analysis. Therefore, some of the centers that perform adult transplant that were identified using the proposed methodology or using option 1 or option 2 may not be eligible to request Medicare approval because they did not perform 9 adult transplants during the 2.5-year period reported in the July 2004 center-specific reports.

NUMBER AND PERCENT OF CENTERS IDENTIFIED AS FAILING TO MEET PROPOSED OUTCOME MEASURE REQUIREMENTS UNDER PROPOSAL AND OPTIONS 1 AND 2, BY ORGAN AND TRANSPLANT TYPE (ADULT OR PEDIATRIC)

Organ type	Number (n) and percent (%) of centers identified using:											
	Adult transplants						Pediatric transplants					
	Proposal		Option 1		Option 2		Proposal		Option 1		Option 2	
	n	%	n	%	n	%	n	%	n	%	n	%
Heart	11	8.7	20	15.9	45	35.7	0	0.0	3	4.4	18	26.5
Liver	11	10.3	15	14.0	43	40.2	3	4.2	4	5.6	19	26.8
Lung	7	10.0	8	11.4	25	35.7	0	0.0	0	0.0	10	100.0
Kidney	25	10.5	42	17.6	112	47.1	3	1.9	6	3.8	160	100.0
All Organs	54	10.0	85	15.7	225	41.6	6	1.9	13	4.2	207	67.0

c. Special Circumstances in Which 1-Month Patient and 1-Month Graft Survival May Be Used in Lieu of 1-Year Patient and 1-Year Graft Survival

We are also proposing that, under certain circumstances, we would review a center's outcomes using 1-month post-transplant data in lieu of 1-year post-transplant data. We recognize that transplant teams sometimes move from one hospital to another to open a new transplant center. It is not uncommon for new centers staffed with an experienced team to have good outcomes. These new centers that request Medicare approval may not have 1-year patient and graft survival data (including follow-up data from at least 9 adult transplants performed during the 2.5-year period reported in the SRTR center-specific reports). At a minimum, 1-month post-transplant data can demonstrate the success of the transplantation procedure as well as the skill of the transplantation team. We believe that in the absence of 1-year post-transplant outcomes, 1-month post-transplant outcomes can capture early graft and patient deaths due to poor transplantation skills and poor donor and/or recipient selection. These data are important in the assessment of a new transplant center.

Therefore, we are proposing that a new transplant center may request initial approval using 1-month patient and 1-month graft survival data if the key members of the center's transplant team performed transplants at a Medicare-approved transplant center for a minimum of 1 year prior to the opening of the new center and if the transplant center's team meets the human resources requirements at § 482.98. If these specific conditions are not met, the new center must be reviewed using 1-year post-transplant patient and graft survival follow-up data. A new center with an experienced team requesting initial Medicare-approval that does not have 1-year patient and graft survival follow-up data (including 1-year follow-up data on at least 9 adult transplants for centers requesting Medicare approval to perform adult transplants) in the most recent SRTR center-specific report would have to ask the SRTR to generate a customized report of the center's 1-month patient and 1-month graft survival statistics for all transplants performed in the previous 1-year period. The SRTR would generate these customized reports using the same models as those used to generate the center-specific reports.

When 1-month post-transplant outcomes are used, we would review the center's 1-month patient and graft survival rates for all transplants performed at the center during the previous 1-year period using customized reports. We would evaluate the center's 1-month outcomes using the same SRTR methodology that we propose for evaluating transplant centers' 1-year outcomes. The transplant center would need to have follow-up data on at least 9 transplants of the appropriate organ type. Instead of 1-year follow-up data on at least 9 transplants performed at the center during the 2.5-year period reported in the SRTR center-specific reports, however, the center would need a customized report with 1-month follow-up data on at least 9 transplants performed during the previous 1-year period.

Centers which gain Medicare approval based on 1 month data would be reevaluated based on 1 year data when it became available. We are requesting comments on the frequency with which we should assess these centers after they are approved.

If a center other than a lung transplant center requests Medicare approval to perform pediatric transplants on the basis of its 1-month patient and graft survival data, we would continue to review the adult and pediatric outcomes separately. We do not propose a volume criterion for approving centers to perform pediatric transplants when a center's 1-year patient and graft survival data are used. Therefore, we do not propose a volume criterion for Medicare approval of a center to perform pediatric

transplants when 1-month patient and graft survival data are used.

4. Proposed Outcome Measure Requirements for Heart-Lung, Intestine, and Pancreas Centers

Due to the limited volume of heart-lung, intestinal, and pancreas transplants performed nationwide, the OPTN has not been able to gather enough transplant data on these organ types for the SRTR to develop Cox models for calculating expected survival statistics for these types of transplants. We prefer not to gauge a transplant center's performance on the basis of unadjusted data. Unadjusted data, or a center's observed outcomes, do not take into account variation among transplant centers, such as differences in patient case-mix. We believe evaluating a transplant center on the basis of unadjusted data could potentially discourage centers from performing transplants on severely ill or high-risk patients. Therefore, for heart-lung, intestinal, and pancreas transplant centers, we propose no outcome measure requirements at this time. In the event that the SRTR develops risk-adjustment models for heart-lung, intestinal, or pancreas transplant survival rates in the future, we will consider establishing outcome measure requirements for heart-lung, intestinal, or pancreas transplant centers through rulemaking.

When the Medicare coverage criteria for heart transplants were published in 1987, heart-lung transplants were considered to be experimental and were not covered by Medicare. When the Medicare coverage criteria for lung transplants were published in 1995, we stated that Medicare would cover heart-lung transplants for beneficiaries with progressive end-stage cardiopulmonary disease when they were provided in a facility that was approved by Medicare for both heart and lung transplantation. Although Medicare began covering heart-lung transplants as well as single and double lung transplants, we did not establish separate survival criteria for heart-lung transplants. Instead, lung centers were required to have an aggregate 1-year survival rate of 69 percent and an aggregate 2-year survival rate of 62 percent. In calculating its survival rates, centers were asked to include single and double lung transplants, as well as heart-lung transplants.

When the SRTR calculates statistics for lung transplants, however, the SRTR does not include heart-lung transplants because there is a separate category of data for heart-lung transplants. Even though the SRTR has a separate category for heart-lung transplant data, the data are not risk-adjusted. We propose that a heart-lung center, as defined in the proposed definition for a ''heart-lung transplant center,'' would need to meet just the proposed data submission requirements to be compliant with the proposed Data Submission and Outcome Requirements for Initial Approval of Transplant Centers CoP. In light of the proposed definition for ''heart-lung transplant center,'' which requires heart-lung centers to be located in a hospital that has Medicare-approval to perform both heart and lung transplants, and the fact that only 33 heart-lung transplants were performed in the U.S. in 2002, we believe that we would have reasonable assurance that the heart-lung center has sufficient expertise to perform heart-lung transplants successfully. We believe skill and expertise in both heart and lung transplantation are sufficient for ensuring that a center is able to perform high quality heart-lung transplants and that separate patient and graft survival rate criteria for heart-lung centers would not be necessary. Again, we request comments on the appropriateness of this approach for evaluating heart-lung transplant centers, as well as alternatives to this approach.

The Medicare coverage decision for multivisceral and intestinal transplants was issued on October 4, 2000 and only covers services provided on or after April 1, 2001. Since only 299 intestinal transplants were performed from 2000 through 2002, it is probable that the current Medicare 1-year patient survival threshold of 65 percent for intestinal transplants continues to be relevant. We are reluctant to establish outcome measure requirements on the basis of unadjusted data. Unlike heart-lung centers, intestinal centers do not have to be affiliated with any other type of center under current Medicare requirements. Historically, however, intestinal centers have evolved as an extension from the liver transplant centers. In 2002, there were 107 intestinal transplants, of which only 44 were intestine alone transplants. Given the historical affiliation of intestinal transplant centers with liver transplant centers and the very small number of intestinal transplants being performed, we are proposing that there not be any outcomes or volume criteria for intestinal transplantation. We believe that the proposed definition for ''intestinal transplant center,'' which requires transplant centers to be located in a hospital that has Medicare approval to perform liver transplants, would be sufficient. Intestinal transplant centers would need to meet the proposed data submission requirements. We are requesting comment on the appropriateness of the proposal to approving intestinal transplant centers in light of the absence of risk-adjusted outcomes data for intestinal transplantation, the very low frequency of this type of procedure, and potential concerns that setting volume standards would further limit access to a rare procedure.

Of the 1,369 deceased donor pancreas transplants performed in the United States in 2003, 502 were performed alone or subsequent to a kidney transplant and 867 were performed simultaneously with a kidney transplant (*i.e.,* kidney-pancreas transplants). According to the July 2003 SRTR national summary report, the national mean 1-year patient survival rate for adult pancreas transplants performed alone or subsequent to a kidney transplant is 96.01 percent and the national mean 1-year graft survival rate is 78.34 percent. Since the number of pancreas transplants performed alone or subsequent to a kidney transplant is very small, the outcomes are generally very good, and the SRTR has not established a risk-adjustment model for pancreas transplants performed alone or subsequent to a kidney transplant, we do not propose any outcome measure requirements for pancreas transplant centers. We believe that the proposed definition for ''pancreas transplant center,'' which requires transplant centers to be located in a hospital that has Medicare approval to perform kidney transplants, would be sufficient. As with heart-lung and intestinal transplant centers, a pancreas transplant center would still need to meet the data submission requirements to be in compliance with the proposed Data Submission or Outcome Requirements for Initial Approval of Transplant Centers CoP at § 482.80. We request comments on the appropriateness of this approach to evaluating pancreas transplant centers in light of the lack of risk-adjusted data for pancreas transplants that are performed alone or subsequent to a kidney transplant.

We note that these standards would not apply to infusions of pancreatic islet cells, a procedure sometimes termed ''islet cell transplantation''. Under section 733 of the Medicare Prescription, Drug Improvement, and Modernization Act (MMA) (Pub. L. 108–173), Medicare pays for some investigational islet transplantation procedures. Our pancreas standards would be inappropriate for these islet procedures which do not involve a whole organ or require the same skills

and expertise as surgical transplantation of whole organs.

D. Summary of Proposed Data Submission and Outcome Measure Requirements for Initial Approval, by Organ Type

Since the requirements proposed in § 482.80 vary by organ type, the following table summarizes the data submission and outcome measure requirements that each type of organ transplant center would have to meet under this proposed CoP.

Type of center	Proposed data submission and outcome measure requirements for initial approval
Heart, Kidney, Liver, or Lung	• Timely submission of at least 95 percent of required data on all transplants[1] performed to OPTN; and • As long as a center has 1-year post-transplant follow-up on at least 9 transplants that were performed during the 2.5-year period reported in the most recent SRTR center-specific report and the center's observed 1-year patient and graft survival rate is higher than its expected 1-year patient and graft survival rate, the center's outcomes would be acceptable. • If the center's observed 1-year patient and graft survival rate is lower than its expected 1-year patient and graft survival rate, the center's patient and graft survival could still be acceptable, unless all 3 of the following thresholds are crossed: (1) p-value < 0.05, (2) O − E > 3, and (3) O/E > 1.5.
Heart-lung	• Timely submission of at least 95 percent of required data on all heart-lung transplants performed to OPTN.
Intestine	• Timely submission of at least 95 percent of required data on all intestinal, combined liver-intestinal, and multivisceral transplants performed to OPTN.
Pancreas	• Timely submission to the OPTN of at least 95 percent of required data on all pancreas and kidney-pancreas transplants performed.

Condition of Participation: Data Submission, and Outcome Measure Requirements for Re-approval of Transplant Centers (Proposed § 482.82)

A. Overview

The current Medicare policies on organ transplants do not have criteria for re-approval of transplant centers. In 2000, 37 percent of Medicare-approved heart transplant centers fell below the Medicare-required volume or survival rate criteria and yet still retained their Medicare-approved status. We believe there is a need to establish criteria for evaluating the ongoing performance of Medicare-approved transplant centers, including post-approval criteria for data submission and outcomes. Without these criteria, we are unable to be assured that once a transplant center becomes Medicare-approved it continues to provide transplantation services in a safe and efficient manner. Given that outcome measures are important indicators of transplantation quality, periodic re-assessment of these indicators, along with the requirement for complete and timely submission of data, would serve as a valuable oversight tool for ensuring that once a transplant center becomes Medicare-approved, it can continually demonstrate a minimum level of commitment to and expertise in transplantation. Therefore, we are proposing specific data submission and outcome requirements for re-approval.

B. Proposed Data Submission Requirements for Re-approval of Transplant Centers

As we proposed for initial approval, we also propose that no later than 90 days after the due date established by the OPTN, heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers must submit to the OPTN at least 95 percent of required data submissions on all transplants (deceased and living donor) performed at the center over the 3-year approval period. As in initial approval, we propose required data submissions include, but not be limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration, and transplant recipient follow-up for the type of organ(s) transplanted.

C. Proposed Outcome Measure Requirements for Re-approval of Transplant Centers

We propose using the same outcome measures for the re-approval of heart, kidney, liver, and lung centers that we propose for initial approval of these centers. However, while we proposed to give transplant centers the option of using 1-month post-transplant outcomes under certain conditions for initial approval, we are not proposing a similar option for re-approval. Each heart, kidney, liver, and lung center would have to use 1-year patient and graft survival data contained in the most recent SRTR center-specific report for re-approval. We would also review outcomes for all transplants performed at the center, including living donor transplants, if applicable.

Furthermore, each heart, kidney, liver, and lung center that has Medicare approval to perform adult transplants would need to have 1-year post-transplant follow-up on at least 9 adult transplants of the appropriate organ type performed during the 2.5-year period reported in the most recent SRTR center-specific report. Except for lung transplant centers, we would review outcomes for pediatric and adult patients separately if a center has Medicare approval to perform pediatric transplants. As with initial approval, transplant centers that have Medicare approval to perform pediatric transplants would not need to perform a minimum number of pediatric transplants. As we stated earlier, requiring centers to perform a minimum number of pediatric transplants would preclude many centers from obtaining Medicare approval to perform pediatric transplants. Again we request comments on our proposed approach to evaluating pediatric transplant centers' outcomes.

For the same reasons discussed for the proposed outcome measure requirements for initial approval, we also propose adopting the same methodology for evaluating a heart, kidney, liver, or lung transplant center's outcomes that we propose for initial approval. As long as the center's

[1] Each transplant center must submit data on all transplants performed at the center, including living donor transplants if applicable, because CMS will review outcomes for all transplants of the appropriate organ type performed at the center.

observed outcomes are higher than the center's expected outcomes, the center's outcomes would be acceptable. If a center's observed outcomes are lower than its expected outcomes, the center's patient and graft survival could still be acceptable, unless all of the following three thresholds are crossed:

- The one-sided p-value is less than 0.05;
- The number of observed events minus the number of expected events (O − E) is greater than 3; and
- The number of observed events divided by the number of expected events (O/E) is greater than 1.5.

Again, we propose that when a center's observed patient and graft survival is lower than the expected patient and graft survival and the center crosses over all three thresholds for a particular outcome measure, we would not consider the center to be in compliance with the requirements for that particular measure. Centers still would have to meet the outcome requirements for each outcome measure separately. In other words, a heart, kidney, liver, or lung center in which both the observed 1-year patient survival rate and the observed 1-year graft survival rates are lower than the expected survival rates would have acceptable outcomes unless the center crosses the thresholds for all three tests (*i.e.*, p-value, O − E, and O/E) with respect to its observed and expected 1-year patient survival rates and with respect to its observed and expected 1-year graft survival rates.

We welcome comments on the proposed thresholds for re-approval of heart, kidney, liver, and lung centers and on the methodology itself. Given that failure to meet the outcome measure requirements would not necessarily result in denial of re-approval, as it would for initial approval, we specifically request comments on whether we should consider a heart, kidney, liver, or lung center's outcomes to be unacceptable if the center crosses the thresholds for all three tests as proposed or whether we should consider a heart, kidney, liver, or lung center's outcomes to be unacceptable if the center crosses the thresholds for just one or two of the three tests, as discussed earlier.

For re-approval of heart-lung, intestinal, and pancreas centers, we propose the same requirements as we do for initial approval of heart-lung, intestinal, and pancreas centers. For heart-lung, intestinal and pancreas transplant centers, we do not propose any outcome measure requirements since we feel that at this time skill and expertise in heart and lung transplantation, in liver transplantation, and in kidney transplantation, respectively, are sufficient. We request comments on our proposed approach to evaluating heart-lung, intestine, and pancreas transplant centers' outcomes.

D. Summary of Proposed Data Submission and Outcome Requirements for Re-Approval, by Organ Type

Since the proposed data submission and outcome requirements for re-approval vary by organ type, the following table summarizes the data submission and outcome measure requirements that each type of organ transplant center would have to meet under this CoP.

Type of center	Proposed data submission and outcome measure requirements for re-approval
Heart, Kidney, Liver, or Lung	• Timely submission of at least 95 percent of required data on all transplants[2] performed to OPTN; and • As long as a center has 1-year post-transplant follow-up on at least 9 transplants that were performed during the 2.5-year period reported in the most recent SRTR center-specific report and the center's observed 1-year patient and graft survival rate is higher than its expected 1-year patient and graft survival rate, the center's outcomes would be acceptable. • If the center's observed 1-year patient and graft survival rate is lower than its expected 1-year patient and graft survival rate, the center's patient and graft survival would still be acceptable, unless all 3 of the following thresholds were crossed: (1) p-value < 0.05, (2) O − E > 3, and (3) O/E > 1.5.
Heart-lung	• Timely submission of at least 95 percent of required data on all heart-lung transplants performed to OPTN.
Intestine	• Timely submission of at least 95 percent of required data on all intestinal, combined liver-intestinal, and multi-visceral transplants performed to OPTN.
Pancreas	• Timely submission to the OPTN of at least 95 percent of required data on all pancreas and kidney-pancreas transplants performed.

Proposed Transplant Center Process Requirements

A. Overview

We believe sound policies and processes are keys to ensuring quality care for patients. State agency surveys of hospitals with transplant centers indicate that deficiencies are usually associated with inadequate or poor implementation of patient management policies and procedures, inadequate staffing, and poor or inadequate monitoring of QAPI programs. We believe it is critical to include process-oriented requirements in the regulation in addition to data submission and outcome requirements. The combination of outcome-oriented and process-oriented requirements will enhance efficient usage of donated organs and thereby decrease organ wastage. The process requirements that we are proposing promote efficiency in the Medicare program and are based heavily on accepted standards of practice in the transplantation field and on continuous quality improvement efforts that have been proven to improve outcomes. To reduce burden on providers, we are revising or eliminating specific requirements that currently apply to heart, kidney, liver, and lung centers and proposing only requirements that will ensure the overall quality of transplant centers for all transplant types. Proposing that transplant centers meet process requirements is intended to promote the quality of transplant services.

The well-being of living donors is as important as the well-being of transplant recipients. Consequently, based on the Secretary's authority under section 1861(e)(9) of the Act to require hospitals to meet requirements ''necessary in the interest of the health and safety of individuals who are

[2] Each transplant center must submit data on all transplants performed at the center, including living donor transplants if applicable, because CMS will review outcomes for all transplants of the appropriate organ type performed at the center.

furnished services in the institution,'' we have proposed several process requirements we believe are necessary to protect the health and safety of prospective living donors.

B. Current Requirements

Currently, kidney transplant centers are covered under applicable regulations in § 405.2135 through § 405.2160 and specific kidney transplant regulations in § 405.2170 through § 405.2171. The current regulations for kidney transplant centers require, among other things, a kidney transplant center to be under the general supervision of a qualified transplant surgeon or a qualified physician-director, serving as the director of renal transplantation and responsible for the following: (1) Participating in the selection of suitable treatment modalities for each patient; (2) ensuring adequate training of nurses in the care of transplant patients; (3) ensuring tissue typing and organ procurement are available either directly or under arrangement; and (4) ensuring transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon(§ 405.2170).

The regulations also require a kidney transplant center to meet specific minimal service requirements: (1) Be part of a Medicare certified and participating hospital; (2) participate in a patient registry program with an OPO certified or recertified under part 486, subpart G ; (3) be under the supervision of the hospital administrator and medical staff; (4) utilize a qualified social worker to evaluate transplant patients' psychosocial needs, participate in care planning of the patients and identify community resources to assist the patient and family; (5) utilize a qualified dietitian who will, in consultation with the attending physician, assess the nutritional and dietetic needs of each patient, prescribe therapeutic diets, provide diet counseling to patients and their families, and monitor adherence and response to a prescribed diet; (6) utilize a laboratory that is approved under 42 CFR Part 493 and that can perform histocompatibility testing on a 24-hour emergency basis, and (7) utilize the services of a designated organ procurement organization(§ 405.2171).

The current Medicare transplant policies for heart, liver, and lung centers have specific process requirements for patient selection, patient management, commitment, facility plans, maintenance of data, organ procurement, laboratory services, and billing.

C. Proposed Process Requirements

Our goals in developing the CoPs are to ensure the quality of care provided in transplant centers and to increase the number of successful transplants. We believe that the OPTN also shares these goals. We believe it will be beneficial for us to adopt certain aspects of the OPTN policies, as they are specific to current practice, in our proposed process requirements. We specifically invite comments on this proposal.

To keep process-oriented requirements to a minimum and to reduce burden on providers, we are proposing only requirements that are directly related to patient outcomes or that are necessary for data collection purposes to ensure the efficient operation of the Medicare program. We propose that our process requirements address the following subjects: (1) Patient and living donor selection, (2) organ recovery and receipt, (3) patient and living donor management, (4) QAPI, (5) human resources, (6) organ procurement, and (7) patients' and living donors' rights, and (8)additional requirements for kidney transplant centers. We want to emphasize that our overall focus is on the continuous, integrated care process that a patient experiences across all aspects of transplantation.

1. Condition of Participation: Patient and Living Donor Selection (Proposed Section 482.90)

[If you choose to comment on this section, please include the caption ''PATIENT AND LIVING DONOR SELECTION'' at the beginning of your comments.]

We believe transplant centers should have an active role in the management of patients prior to transplantation. We propose to require centers to utilize written patient selection criteria in making determinations regarding a patient's suitability for placement on the waitlist and a patient's suitability for transplantation. When a patient is placed on the center's waitlist or is selected to receive a transplant, we propose that the center must document in the patient's medical record the patient selection criteria that were utilized. We are also asking for comments on whether transplant centers should be required to make the patient selection criteria available to patients, either routinely or upon request.

We have not specifically defined patient selection criteria in the proposed rule because transplant technology is continually changing. We want to preserve centers' flexibility in identifying organ transplants that are medically reasonable and necessary in light of the most recent transplantation research and the needs of transplant recipients. However, we propose that the patient selection criteria must ensure fair and non-discriminatory distribution of organs.

In general, organ transplants, should be performed only on carefully selected patients whose medical needs cannot be met by other therapies (except for kidney transplants where the dialysis option may continue to exist). We propose that before a transplant center selects a patient for extra-renal transplant, the center would have to consider or employ all other appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplantation.

We are proposing an exception to this patient selection requirement for kidney transplant candidates because while kidney transplantation is the preferred treatment for patients with kidney failure, ESRD patients, unlike patients with other types of end-stage organ failure, have an alternative dialysis treatment option available to them, when kidney transplant is not feasible or when the graft has failed. Renal replacement therapy, which is required when kidney functions fall below 10–15 percent, includes either dialysis or kidney transplants.

Studies have shown that dialysis does not seem to yield survival comparable to transplantation. Kidney transplantation has many advantages, such as a lifestyle free from dialysis, a better quality of life and a longer life expectancy. However, kidney transplants have risks, such as surgical complications, rejection, and life-long maintenance medications and associated side effects. Therefore, dialysis continues to be a viable treatment option for an ESRD patient whose kidney transplant was unsuccessful.

We propose that a prospective transplant candidate must receive a psychosocial evaluation prior to placement on the waitlist. Although a person may be medically suitable for transplantation, he or she may have inadequate social support or coping abilities, or may be unable to demonstrate adequate adherence to a therapeutic regimen, which could then put the graft, and ultimately the transplant recipient at risk.

We also propose that before a transplant center places a patient on its waitlist, the candidate's medical record would have to contain documentation that the candidate's blood type has been determined. Requiring documentation

of the candidate's blood type would ensure that transplant centers are verifying the accuracy of vital data necessary to match the transplant candidate to a potential donor. We are specifically requesting comments on this proposal.

Like organ transplant candidates, we believe potential living donors should be carefully selected. Unlike deceased donor transplantation, living donor transplantation presents an ethical quandary in that living donation represents the only area of medicine in which an otherwise healthy individual is subject to surgical risk for somebody else's benefit. Any benefits to the donor are primarily psychological. We propose that transplant centers performing living donor transplants would have to use written living donor selection criteria to determine the suitability of candidates for living donation. We propose that the center must document in the transplant candidate's and living donor's medical records the living donor's suitability for donation. We have not proposed specific living donor selection criteria for transplant centers because there are no established guidelines concerning the selection of living donors at this time. Until living donor standards are established, we propose that the centers' living donor selection criteria must be consistent with the general principles of medical ethics. We propose that prior to donation, a prospective living donor must receive a medical and psychosocial evaluation. We also propose that the transplant center must document that the living donor has given informed consent, as required under § 482.102.

2. Condition of Participation: Organ Recovery and Receipt (Proposed Section 482.92)

As reported in The *Charlotte Observer,* a recent death of a transplant recipient was caused by transplantation of organs from a donor of an incompatible blood type. The incident was attributed to a combination of system errors that occurred during the organ procurement, organ receipt, and transplant processes. Another death was attributed to a miscommunication of blood types between the center's laboratory and the transplant team (Grady, Denise and Lawrence K. Altman, ''Suit Says Transplant Error Was Cause in Baby's Death in August,'' *The New York Times,* 12 March 2003, Section A, Page 23, Column 5). These two events might have been avoided if certain steps were actively taken to validate the ABO (*i.e.* blood type) compatibility and other key data elements.

Under the current policies for heart, liver and lung transplants and the current regulations for renal transplant centers, there are no provisions addressing procedures for transplant centers to ensure that donor organ and transplant recipient data are compared, or to prevent the transplantation of mismatched organs. The OPTN rules specify that an OPO with an organ available for transplantation must obtain a ''match run'' for that organ type from UNOS. The match run lists potential recipients on the waitlist who are the correct size and blood type to receive the organ that is available. The OPTN also requires the OPO to provide the transplant center with written documentation of the potential donor's age, sex, and race, appropriate laboratory values, blood type, ABO or HLA typing, vital signs, cause of brain death and diagnosis, and current medication and transfusion history. However, these OPTN policies are voluntary. To prevent transplant mishaps caused by blood type mismatch, we propose that transplant centers would need to have written protocols for organ recovery and organ receipt. We propose that the protocols would have to ensure that the transplant center validates the donor's and the recipient's blood type and other vital data. Examples of vital data about the donor and the recipient that a transplant center should validate include, but are not limited to, appropriate laboratory values, vital signs, current medication and transfusion history. We also propose assigning responsibility for ensuring the medical suitability of donor organs for transplantation into the intended recipient to the transplanting surgeon, or the surgeon in the transplant center receiving the organ offer for his or her patient.

We propose that a center's protocols for organ recovery specify that a transplant center's organ recovery team would have to review and compare the recipient and donor data before recovery takes place. We also propose that when an organ arrives at the center, the transplanting surgeon and at least one other individual at the transplant center would have to verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient prior to transplantation. These verifications would ensure that transplant centers are actively taking steps to avoid transplantation of mismatched organs throughout the organ distribution process and would also prevent wastage of organs in the event a mismatch was not discovered until the organ(s) arrived at the transplant hospital.

We also propose that a center's protocols for organ recovery and receipt would have to ensure that the transplanting surgeon and at least one other individual at the transplant center verifies that the living donor's vital data (including blood type) are compatible for transplantation of the intended recipient, immediately before the removal of the living donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

3. Condition of Participation: Patient and Living Donor Management (Proposed Section 482.94)

Under the current policies for heart, liver and lung transplants, a center is required to have adequate patient management plans and protocols that include therapeutic and evaluative procedures during the waiting, in-hospital, and discharge phases of transplantation. The current conditions for coverage for ESRD services require each ESRD facility, which includes renal transplant centers, to maintain for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. We believe that a patient's care should be managed during every stage of transplantation, starting with the patient's evaluation for placement on a center's waitlist and through the patient's discharge from the hospital following transplant, to ensure that the services provided meet the patient's care needs and that the patient is involved in his or her care. We propose that centers must have written patient management policies and patient care planning for pre-transplant, and through the patient's discharge from the hospital following transplant. It is equally important to ensure that living donors receive services that meet their care needs throughout the various stages of donation, starting with donor evaluation and continuing through the donor's immediate discharge from the hospital post-donation. Therefore, we propose that centers performing living donor transplants must have written donor management policies for the donor evaluation, donation, and through the donor's discharge from the hospital following donation. We propose that a transplant center must ensure that each patient or living donor is under the care of a multidisciplinary patient care team coordinated by a physician during all phases of transplantation or living donation.

A center's initial responsibility for a transplant patient begins when he or she is evaluated for placement on that center's waitlist, regardless of whether or not the patient is on another center's waitlist. Effective waitlist management, in our view, means installing and maintaining a reliable administrative system that tracks patient status and provides accurate updated patient data on demand. Inaccurate information on waitlist patients may create a situation where a center may initially agree to accept organs that are offered to them but later decline them at the last minute when they discover that the organs are not suitable for the intended recipients. In order to prevent organs from being wasted once they are recovered, we are proposing a standard specifically for waitlist management.

In 2002, the Clinical Practice Committee of the American Society of Transplantation issued guidelines regarding waitlist maintenance based on a questionnaire sent out to 287 transplant centers, of which 192 responded. The guidelines specifically recommend annual follow-up or assessment of potential transplant recipients as deemed appropriate to ascertain transplant status. Although we do not specifically propose annual follow-up or assessment of transplant candidates, we believe transplant centers need to reassess patients placed on their waitlist to ensure that (1) the center's information on the patient is accurate and (2) the transplant is still medically indicated. We are proposing that transplant centers keep their waitlists up to date, including updating waitlist patients' clinical information on an ongoing basis. We also propose that the transplant center must remove a patient from its waitlist when the patient receives a transplant or dies, or if there is any other reason why the patient should no longer be placed on a center's waitlist (for example, the patient's health could deteriorate or improve to the point that a transplant would no longer be medically suitable or a patient could voluntarily ask to be removed from a center's waitlist). We propose requiring transplant centers to notify the OPTN of the patient's removal from the center's waitlist no later than 24 hours after such removal. This timely notification to the OPTN of a patient's removal from a center's waitlist is crucial. Not only would this notification provide patients with confirmation of their removal from a center's waitlist, but the OPTN would also rely on this information to keep the national waitlist current. Prompt notification of a patient's removal from the waitlist provides more accurate data to facilitate accurate patient placement on the waitlist. Prompt notification of patient's removal from a center's waitlist would also enhance the accuracy of the SRTR data analyses. Furthermore, OPOs have a very narrow window of opportunity for allocating recovered organs to the appropriate recipient. Some OPOs have complained that transplant centers sometimes agree to accept an organ for a particular individual only to discover later that the individual has already received a transplant or has died prior to receiving a transplant.

We are proposing a requirement at § 482.94(c) that transplant centers maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplant. We believe that accurate patient records are especially crucial in determining a patient's readiness for transplants. Accurate information about a patient's transplant status needs to be readily available to individuals involved in the care of the patient, and to the patients themselves. For example, we have found that in some cases, after a kidney dialysis patient is evaluated for placement on a center's waitlist, the patient's status is not communicated to the dialysis facility or to the patient. The patient, and the dialysis facility, may believe he or she has been placed on a waitlist, only to find months later that the transplant center is waiting for the patient to undergo further clinical testing.

Given that time on the waitlist is often one of the factors that determine which patients ultimately are transplanted, we propose that for each patient who has received an evaluation for placement on a center's waitlist, the transplant center must document in the patient's record that it has notified each patient of his or her placement status. Specifically we propose that the center must notify the patient of: (1) The patient's placement on the center's waitlist; (2) the center's decision not to place the patient on its waitlist; or (3) the center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed.

After a patient is placed on a center's waitlist, we believe it is the transplant center's responsibility to provide waitlisted patients with an annual update of their waitlist status. We propose that once a patient is placed on a center's waitlist, the center must document in the patient's record that the patient has been notified of his or her waitlist status at least once a year, even if there is no change in the patient's placement status. In addition, we propose that no later than 10 days after a patient's removal from a center's waitlist for reasons other than death or transplantation (such as the patient's voluntary withdrawal from the waitlist or a change in the patient's medical status such that a transplant is no longer indicated), the center must document in the patient's record that the patient has been notified of his or her removal from the waitlist. For dialysis patients, we propose that the transplant center also must document in each patient's record that both the patient and the patient's usual dialysis facility are informed of the patient's transplant status or of changes in the patient's transplant status. In the event there are changes in a dialyzed patient's transplant status, we believe it is imperative for dialysis facilities to have up-to-date and accurate information about kidney transplant candidates to ensure adequate care and coordination between the dialysis facility and the transplant center prior to transplantation. In the case of patients admitted for organ transplants, we propose that the patient records contain written documentation of multidisciplinary care planning during the pre-transplant period and multidisciplinary discharge planning for the patient's post-transplant care.

In addition, we propose requiring transplant centers to make available social and nutritional services, furnished by qualified social workers and dietitians, to patients and living donors. The current kidney transplant center regulations at § 405.2171 require centers to provide a qualified social worker to evaluate transplant patients' psychosocial needs, participate in care planning of patients, and identify community resources to assist the patient and family. Similarly, we believe social services, such as assisting and supporting patients and their families in maximizing the social functioning and adjustment of the patient, are important to all transplant patients and living donors. Therefore, we are proposing that social services, furnished by a qualified social worker, be made available to all transplant patients, living donors and their families. Based on the definition of ''qualified social worker'' contained in § 405.2102, we propose to define a qualified social worker as an individual who meets licensing requirements in the State in which practicing, and (1) has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the

Council on Social Work Education; or (2) has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who has obtained the education described above.

The current kidney transplant center regulations at § 405.2171 also require a qualified dietitian, in consultation with the attending physician, to assess the nutritional and dietetic needs of each patient, recommend therapeutic diets, counsel patients and their families on prescribed diets and monitor adherence and response to diets. All transplant patients and living donors may need dietary modifications, permanently or temporarily, to maintain balances in fluids, electrolytes, and macro or micro-nutrients. We are proposing that nutritional assessments and diet counseling, furnished by qualified dietitians be made available to all transplant patients and living donors. Based on the definition of ''qualified dietitian'' contained in § 405.2102, we propose to define a qualified dietitian as an individual who (1) is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976 and who has at least 1 year of experience in clinical nutrition; or (2) has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

4. Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (Proposed Section 482.96)

QAPI is the process of using objective data to study and continually make improvements to all aspects of an organization's operations and services. QAPI rests on the assumption that an organization's own quality management system is the key to improved performance. It seeks to increase the amount and quality of information on which to base decisions and improve quality.

We believe that QAPI is regarded by the health care community as the most efficient and effective method for improving the quality and performance of health care providers. Most transplant centers, by virtue of being part of a hospital, already participate in QAPI programs because, in addition to being required by our regulations at § 482.21, QAPI is a process required by JCAHO through its hospital accreditation standards. Although the transplant hospital's QAPI program may not contain elements that are specific to the transplant center, many transplant centers have voluntarily established strong QAPI programs and utilize them to effect change within the transplantation system. However, transplant centers' QAPI programs vary in their sophistication and scope.

Therefore, we are proposing a requirement that every transplant center develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate all transplantation services, including services provided under contract or arrangement. These requirements are based on our commitment to encouraging continuous quality improvement for all Medicare providers and suppliers. A requirement for transplant centers to have a QAPI program will encourage continuous quality improvement at the center level, as well as the use of best practices, as determined by the individual centers and the transplant community.

We do not intend to stipulate specific activities a transplant center must include in its QAPI program. We propose requiring a transplant center's QAPI program to use objective measures to evaluate improved performance with regard to transplant activities. Areas to be evaluated would include patient and donor selection criteria, accuracy of the waitlist in accordance with the OPTN waitlist, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient satisfaction and patient rights. We propose that the transplant center would be required to take actions that result in performance improvements and track performance to ensure that improvements are sustained.

As part of the QAPI process, a transplant center would be required to establish and implement a written policy to address adverse events that occur during any phase of the organ transplant process. The policy must address at a minimum, the process for identification, reporting, analysis, and prevention of adverse events. An adverse event for a transplant center could be, for instance, living donor death due to mismanagement of a donor; transplantation of organs of mismatched blood types due to failure to validate donor and recipient's vital information; or transplanting organs to unintended recipients. Examples of situations involving direct patient outcomes that might qualify as adverse events include: (1) Avoidable loss of a healthy living donor; and (2) unintended transmission of infectious disease to a recipient.

In addition, we are proposing that transplant centers would be required to conduct a thorough analysis of and document any adverse event and to utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents. We believe that the formal analysis is essential to examining a transplant center's existing policies and practices, improving the organ transplantation process, and improving efficiency and outcomes.

5. Condition of Participation: Human Resources (Proposed Section 482.98)

[If you choose to comment on this section, please include the caption ''HUMAN RESOURCES'' at the beginning of your comments.]

We propose that transplant centers ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services. Currently, the ESRD regulations require a renal transplant center to be under the general supervision of a qualified transplant surgeon or qualified physician-director, who is responsible for planning, organizing, and directing the renal transplant center and devotes sufficient time to carry out certain responsibilities. We believe that all transplant centers should be directed by a qualified transplant surgeon or physician. Therefore, we propose at § 482.98(a) that each transplant center would have to be under the general supervision of a qualified transplant surgeon or a qualified physician-director.

The director of a transplant center would be responsible for planning, organizing, conducting, and directing the transplant center and would have to devote sufficient time to carry out these responsibilities. Specific responsibilities would include, but not be limited to, ensuring adequate training of nursing staff in the care of transplant patients; ensuring tissue typing and organ procurement services are available; and ensuring that transplantation surgery is performed under the direct supervision of a qualified transplant surgeon in accordance with § 482.98(b). The director of a transplant center would not need to serve in such capacity full-time and may also serve as the center's primary surgeon or physician, as discussed below. Since this would be a new requirement for extra-renal transplant centers, we request comments regarding whether it is necessary to require each transplant center to have a director to oversee the center, in addition to other human resources requirements.

We propose at § 482.98(b) that transplant centers must identify to the OPTN both a primary transplant surgeon and a primary transplant physician with the appropriate training and experience to provide transplantation services. For example, we would consider a transplant surgeon or transplant physician that meets the OPTN's policies regarding the training and experience of transplant surgeons and transplant physicians to have the appropriate training and experience to provide transplantation services. The transplant surgeon would be responsible for providing surgical services related to transplantation while the transplant physician would be responsible for providing and coordinating transplantation care.

In addition, we propose that transplant centers have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. Many transplant centers have clinical transplant coordinators on their teams to ensure coordination and continuity of care before patients are transplanted, while they are hospitalized for the transplant, and following the transplant. We propose that a qualified clinical transplant coordinator would have to be certified by the American Board of Transplant Coordinators (ABTC) which requires at least 12 months of work experience as a transplant professional in vascular organ transplantation and successful completion of the certification examination. We believe ABTC certification ensures that an individual serving in the capacity of a clinical transplant coordinator has met a standard of competency and possesses the necessary knowledge and skills needed to provide quality care for transplant recipients and donors. Clinical transplant coordinators are usually charged with the responsibilities of: (1) Educating patients, living donors, and families about treatment options, and post-operative care or therapies; (2) monitoring patients' and living donors' medical, surgical and psychosocial status; and (3) providing feedback to other team members. We request comments concerning whether an alternative set of training and experience standards should be used for qualified clinical transplant coordinators.

In addition, we propose that a transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. We propose that the team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination and pharmacology. For example, a transplant team in a liver center should be composed of individuals with training and experience to treat and care for patients with end-stage liver disease and not ESRD patients. We have proposed this requirement to ensure that transplant centers have the ability to provide the services necessary to meet all of a transplant patient and a living donor's medical and psychosocial needs. We also believe that a transplant center must make a sufficient commitment of resources and planning to its transplantation program. We propose that a transplant center must demonstrate the availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease, pathology, radiology, and blood banking as related to the provision of transplantation services.

6. Condition of Participation: Organ Procurement (Proposed Section 482.100)

In this proposed rule, we are also proposing to require that transplant centers ensure that the transplant hospital in which the center operates has a written agreement for the receipt of organs with an OPO designated by the Secretary. We propose at § 482.100 that the transplant center would have to ensure that the transplant hospital-OPO agreement identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation. In the event that a transplant hospital terminates any agreement with an OPO or an OPO terminates any agreement with the transplant hospital, we propose that the transplant center must notify us in writing no later than 30 days after the termination of the agreement.

7. Condition of Participation: Patients' and Living Donors' Rights (Proposed Section 482.102)

[If you choose to comment on this section, please include the caption ''PATIENTS' AND LIVING DONORS' RIGHTS'' at the beginning of your comments.]

In addition to meeting the general hospital requirements for patients' rights in 42 CFR 482.13, we propose that a transplant center must protect and promote each transplant patient's and living donor's rights. Prior to transplantation or living organ donation, transplant centers must inform patients (including living donors) of their rights.

There are some unique aspects of transplantation and living donation that make patient rights, particularly informed consent, critical. Hence, we propose requiring transplant centers to have a written informed consent process that addresses these unique aspects of transplantation and living donation. For example, the critical shortage of donor organs nationwide has caused transplant centers, researchers, and OPOs to investigate the potential of ''extended criteria organs'' to increase the supply of organs available for transplantation. Only a decade ago, these organs would not have been deemed usable due to the donor's age or health, or the condition of the organ. Such extended criteria organs included livers with excess fat, kidneys with extended cold ischemia time, or organs from donors 70 years of age or older. Although surgeons once rejected such organs, they now may choose to transplant them. Advances in transplant technology and skills, immunosuppressive drugs, improved infection management, and careful donor and recipient selection in combination with our national donor shortage have helped relax the criteria for accepting donor organs. The use of organs from extended criteria donors is now viewed as a viable alternative for patients with medical urgency. Although we agree that extended criteria donors can help to expand the donor pool, we believe it is important that patients be informed that organs from extended criteria donors could affect the success of the graft or the health of the patient.

We propose that the transplant center's written informed consent process notify transplant patients of information about all aspects of and potential outcomes from transplantation, including, but not limited to: (1) The evaluation process; (2) the surgical procedure; (3) alternative treatments; (4) potential medical or psychosocial risks; (5) national and transplant center-specific outcomes, such as graft and patient survival; (6) the fact that future health problems related to the transplantation may not be covered by the recipient's insurance and that the recipient's ability to obtain health, disability, or life insurance may be affected; (7) organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used or the patient's possible risk of contracting the human

immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor; and (8) the right to refuse transplantation.

OPOs make every effort to obtain a social/behavioral history for each potential donor from the next-of-kin or other knowledgeable individual. If a potential donor has engaged in a behavior that would have put him or her at high risk of contracting an infectious disease, such as HIV or hepatitis (for example, injecting illegal drugs), donation generally is ruled out, unless the risk to the recipient of not performing a transplant is greater than the risk of contracting an infectious disease. In such case, informed consent regarding the possibility of transmission of infectious disease must be obtained from the transplant recipient.

In 2002, there was a case in Oregon in which hepatitis C was transmitted to transplant recipients that received organs from an individual who tested ''negative'' for hepatitis C at the time of donation. After further investigation, it was determined that the recipients became infected with hepatitis C because the donor had been infected with the disease but had not built up enough antibodies to test ''positive'' for the disease at the time of donation. If a donor's social history (*e.g.*, history of drug use, sexual history, etc.) indicates that the donor could potentially be in a ''window'' period for transmitting HIV, hepatitis C, hepatitis B, or other infectious diseases, we believe that the patient's informed consent should also include this information. In other words, transplant patients should be notified when they are receiving organs from high-risk donors and should be notified that they may be at risk of contracting these diseases by accepting the donated organs. Examples of high-risk donors include, but are not limited to, donors who have tested ''negative'' for an infectious disease but whose social history indicates that the donor is at high risk for contracting the disease. In notifying transplant patients about a donor's history, we would expect the transplant center to do so in a manner that would keep the identity of the donor confidential. Given that it is difficult to predict whether a high-risk donor could be in a ''window'' period, and that there is no national standard guiding the use of organs from extended criteria donors, and that some patients can afford to wait for a healthier organ that may become available later, we are soliciting comments on our proposal of the requirements to inform patients of potential risks.

Recently, the ACOT developed a set of recommendations for living donors at the Secretary's request. ACOT has agreed upon a set of ''Ethical Principles of Consent to Being a Live Organ Donor.'' The principles state that the person who gives consent to becoming a live organ donor must be:

- Competent (possessing decision making capacity),
- Willing to donate,
- Free from coercion,
- Medically and psychosocially suitable,
- Fully informed of the risks and benefits as a donor, and
- Fully informed of the risks, benefits, and alternative treatment available to the recipient.

ACOT also endorsed two other ethical principles:

- Equipoise; that is, the benefits to both the donor and the recipient must outweigh the risks associated with the donation and transplantation of the live donor organ; and
- A clear statement that the potential donor's participation must be completely voluntary, and may be withdrawn at any time.

ACOT further recommends that the following ''Standards of Disclosure: Elements of Informed Consent'' be incorporated into the informed consent document given to the potential live organ donor, with specific descriptions that would ensure the donor's awareness of:

- The purpose of the donation,
- The evaluation process—including interviews, examinations, laboratory tests, and other procedures—and the possibility that the potential donor may be found ineligible to donate,
- The donation surgical procedure,
- The alternative procedures or courses of treatment for potential donor and recipient,
- Any procedures which are or may be considered to be experimental,
- The immediate recovery period and the anticipated post-operative course of care,
- The foreseeable risks or discomforts to the potential donor,
- The potential psychological effects resulting from the process of donation,
- The reported national experience, transplant center and surgeon-specific statistics of donor outcomes, including the possibility that the donor may subsequently experience organ failure, disability and death,
- The foreseeable risks, discomforts, and survival benefit to the potential recipient,
- The reported national experience and transplant center statistics for recipient outcomes, including failure of the donated organ and the frequency of recipient death,
- The fact that the potential donor's participation is voluntary, and may be withdrawn at any time,
- The fact that the potential donor may derive a medical benefit by having a previously undetected health problem diagnosed as a result of the evaluation process,
- The fact that the potential donor undertakes risk and derives no medical benefit from the operative procedure of donation,
- The fact that unforeseen future risks or medical uncertainties may not be identifiable at the time of donation,
- The fact that the potential donor may be reimbursed for the personal expenses of travel, housing, and lost wages related to donation,
- The prohibition against the donor otherwise receiving any valuable consideration (including monetary or material gain) for agreeing to be a donor,
- The fact that the donor's existing health and disability insurance may not cover the potential long-term costs and medical and psychological consequences of donation,
- The fact that the donor's act of donation may adversely affect the donor's future eligibility for health, disability, or life insurance,
- Additional informational resources relating to live organ donation (possibly through the establishment of a separate resources center, as recommended below.
- The fact that by donating, the donor authorizes Government approved agencies and contractors to obtain information regarding the donor's health for life, and
- The principles of confidentiality, clarifying that:

—Communication between the donor and the transplant center will remain confidential;
—A decision by the potential donor not to proceed with the donation will only be disclosed with the consent of the potential donor;
—A transplant center will only share the donor's identity and other medical information with entities involved in the procurement and transplantation of organs, as well as registries that are legally charged to follow donor outcomes; and
—Confidentiality of all patient information will be maintained in accordance with applicable laws and regulations.

We recommend that transplant centers that perform living donor transplants consider the ACOT's recommendations in developing informed consent policies for living donors. Transplant centers may also

wish to review two specific informed consent documents developed by ACOT. The first relates to the potential donor's initial consent for evaluation as a possible donor, *''Living Liver Donor Initial Consent for Evaluation.''* The second deals with the potential donor's informed consent for surgery, *''Living Liver Donor Informed Consent for Surgery.''* These documents are available on the Department's organ donation Web site at *http://www.organdonor.gov.*

Although the proposed requirements for informed consent incorporate some of the ''Standards of Disclosure'' recommended by ACOT, we are not proposing to require that transplant centers include all of these standards in their informed consent process for living donors. To serve the best interest of living donors, we are proposing at § 482.102(b) that transplant centers implement a written informed consent process for living donors that inform potential living donors about all aspects of and potential outcomes from living donation. Specific issues on which potential living donors would have to be informed of include, but are not limited to: (1) The fact that communication between the donor and the transplant center will remain confidential in accordance with the Department's Health Information Privacy Rules (45 CFR parts 160 and 164); (2) the evaluation process; (3) the surgical procedure, including post-operative treatment; (4) the availability of alternative treatments for the transplant recipient; (5) the potential medical or psychosocial risks to the donor; (6) the national and transplant center-specific outcomes such as graft and patient survival for both donors and recipients; (7) the possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected; and (8) the donor's right to opt out of donation at any time during the donation process. We request comments regarding our proposed informed consent requirements for living donors, including those requirements we have adopted from the ACOT recommendations, and whether we need to establish additional criteria for transplant centers performing living donor transplants (such as, incorporating other ACOT recommendations).

In addition to requesting assistance in improving the lives of recipients and protecting living organ donors, the Secretary also requested that ACOT consider the desirability of an independent donor advocate (or advocacy team) to represent and advise the donor so as to ensure that the previously described elements and ethical principles are applied to the practice of all living donor transplantation. ACOT has provided detailed recommendations as to how such an independent donor advocate should be established, as well as the role and qualifications of such an advocate. ACOT recommended that each transplant center identify and provide to each potential donor an independent and trained patient advocate whose primary obligation would be to help donors understand the process, the procedure and risks and benefits of living organ donation; and to protect and promote the interests and well-being of the donor. We believe that a living donor advocate (or advocacy team) would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. We are requesting comments on whether we should include a requirement for transplant centers performing living donor transplants to provide the service of an independent donor advocate (or advocacy team) and what the individual or team's credentials should be.

Additionally, we believe that waitlist patients need to be informed of circumstances within a transplant center that may impact their ability to receive a transplant should an organ become available and what procedures are in place to ensure coverage. Thus, we are proposing that a transplant center served by a single transplant surgeon or physician must inform its patients of this fact and of the potential unavailability of the transplant surgeon or physician should an organ become available for the patient. If a transplant center is served by a single transplant surgeon or physician, we also propose that the center inform its patients whether or not the center has a mechanism for providing an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies should the center's transplant surgeon or physician be unavailable.

It is not our intent to disrupt the availability of covered organ transplants for Medicare beneficiaries. Therefore, in the event that termination becomes imminent during the 3-year approval period, we are proposing at least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, that the center must inform the patients on the waitlist and must provide assistance to patients who choose to transfer to another Medicare-approved center without loss of the patient's time accrued on the waitlist. (The OPTN controls the nation's organ transplant waitlist and has rules to ensure that a patient who transfers from one waitlist to another does not lose any accrued time.) Generally speaking, we do not believe transferring patients from the waitlist of a center that is facing loss of its Medicare approval to an open center's waitlist would increase the length of wait for others already on the open center's waitlist because time on the waitlist is just one of several factors that are used to match donor organs to a potential transplant recipient.

We also propose that at least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center would have to inform all Medicare beneficiaries added to the waitlist that Medicare will not pay for transplants performed at the center after the effective date of the center's loss of approval. We are proposing these requirements to ensure that patients on the center's waitlist do not lose precious waiting time as a result of a center's loss of approval.

8. Condition of Participation: Additional Requirements for Kidney Transplant Centers (Proposed Section 482.104)

In addition to meeting the special requirements for transplant centers (proposed § 482.68), we also propose additional requirements for kidney transplant centers. As stated previously, we propose to delete § 405.2120 through § 405.2134, § 405.2170 through § 405.2171, and the definitions for ''histocompatibility testing,'' ''ESRD Network,'' ''ESRD network organization,'' ''organ procurement,'' ''renal transplantation center,'' ''transplantation service,'' and ''transplantation surgeon'' contained in § 405.2102. We propose to retain some of these requirements at § 482.104.

Specifically, we propose that kidney transplant centers must furnish directly, transplantation and other medical and surgical specialty services required for the care of the ESRD patients, including inpatient dialysis, either directly or under arrangement. We propose that the dialysis services furnished by transplant centers would have to be furnished in accordance with part 405, subpart U of this chapter. We propose that kidney transplant centers must cooperate with the ESRD Network designated for its geographic area in fulfilling the terms of the network's current statement of work.

Special Procedures for Approval and Re-Approval of Transplant Centers

Currently, a facility's application to become a Medicare-approved heart, liver, or lung transplant center is evaluated with the aid and advice of non-Federal expert consultants. Generally, the consultants are responsible for reviewing applications at our request, making recommendations to us concerning qualified centers and supporting each recommendation with written documentation. CMS reviews intestinal transplant center applications for Medicare approval. For kidney transplant centers, the CMS Regional Offices review and process requests for Medicare approval.

This proposed rule introduces facility criteria for heart-lung and pancreas transplant centers and changes the process for reviewing applications for approval of heart, intestine, kidney, liver, and lung transplant centers. The current facility criteria for heart, intestine, kidney, liver, and lung centers and the process for reviewing applications for approval of heart, intestine, kidney, liver, and lung transplant centers contained in the Medicare coverage policies and the regulations at 42 CFR part 405, subpart U would continue to be in effect until we announce otherwise. We propose that once this proposed rule is finalized, we, or our designee (*e.g.*, a State survey agency or an accreditation organization with deeming authority for hospitals, such as the JCAHO or AOA), would have responsibility for monitoring and coordinating the procedures for approval or re-approval of a transplant center. For the purpose of approving and re-approving transplant centers, we propose at § 488.61 that we utilize the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A, including the periodic review of compliance and approval contained in § 488.20.

Last year, Congress passed the MMA. Section 901(b) of the MMA, adding new paragraph 1861(d) to the Act, states that ''[t]he term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.'' Section 936 of the MMA added new section 1866(j) to the Act, which, among other things, gives both providers (as defined at section 1861(u) of the Act) and suppliers (as defined above) the right to seek judicial review of certain adverse agency decisions regarding enrollment and re-enrollment.

We believe that transplant centers are unique entities that do not fit perfectly into either the provider or supplier category. There is no enrollment process involved. A transplant center is an optional status based on conditions that are applicable only to Medicare hospitals that choose to apply for Medicare approval as a transplant center. A Medicare-approved transplant center must first meet all of the hospital CoPs in 42 CFR part 482, which serves as the basis of survey activities for the purpose of determining whether a hospital qualifies for a Medicare provider agreement. Thus, a Medicare-approved transplant center must be operated within a provider as defined in section 1861(u) of the Act (*i.e.*, a Medicare hospital).

However, ''transplant center'' is not listed in the definition of ''provider'' under section 1861(u) of the Act. By virtue of the fact that a transplant center is an entity other than a provider (as defined in section 1861(u) of the Act), we could argue that ''transplant center'' falls under the definition of ''supplier'' created in section 901 of the MMA. Given the unique nature of transplant centers, we are requesting comments on the appropriate appeals mechanism for transplant centers. Specifically, we are interested in receiving comments regarding whether transplant centers should be regarded as ''providers'' or as ''suppliers'' for the purpose of appealing adverse approval and re-approval decisions. We believe that regardless of whether we define a transplant center to be a ''provider'' or a ''supplier,'' it is necessary to have some type of appeal process in the event that CMS decides to not approve or re-approve a hospital's transplant center.

[If you choose to comment on this issue, please include the caption ''PROVIDER VS. SUPPLIER STATUS FOR APPEALS'' at the beginning of your comments.]

A. Initial Approval Procedures

We propose at § 488.61(a) that a transplant center can submit a letter of request to CMS for Medicare approval at any time. We are not proposing any particular formal application. The letter, signed by a person authorized to represent the hospital (for example, a chief executive officer), would need to include the hospital's Medicare provider I.D. number, name(s) of the designated primary transplant surgeon and primary transplant physician and a statement from the OPTN that the center has complied with all data submission requirements.

We propose to determine a heart, heart-lung, intestine, kidney, liver, lung, or pancreas transplant center's compliance with the data submission and outcome requirements proposed at § 482.80 by reviewing the center's data. For compliance with the data submission requirements, we would expect the OPTN to review its statistics on data completeness for the previous calendar year and certify compliance with the data submission requirements. For compliance with the outcome measures requirements, we would review the 1-year patient and graft survival data contained in the most recent SRTR center-specific report unless the center is eligible for initial approval on the basis of its 1-month patient and graft survival. If 1-month patient and graft survival data are used, we would review the customized reports prepared by the SRTR for the previous 1-year period. The center would be responsible for requesting the SRTR to prepare these customized reports.

The SRTR center-specific reports are updated every six months (currently, the reports are updated in January and July of each year). If, for example, we receive a letter from a transplant center requesting Medicare approval on October 1, 2006, we would review the center's 1-year patient and graft survival statistics from the SRTR's July 2006 reports, which includes 1-year graft and patient survival statistics on transplants performed anywhere between 1 to 3.5 years previously. As we have stated previously, we will be reviewing the post-transplant outcomes for all transplants, including living donor transplantation, performed at a center during the 2.5-year period in which the outcomes are reported.

However, a new transplant center may request initial Medicare approval using 1-month patient and 1-month graft survival data if the key members of the center's transplant team performed transplants at a Medicare-approved transplant center for a minimum of 1 year prior to the opening of the new center and if the transplant center's team meets the human resources requirements at § 482.98. We would review the 1-month patient and graft survival data on at least 9 transplants performed during the previous 1-year period captured in the customized reports prepared by the SRTR.

If a center requires Medicare approval to perform pediatric transplants, the center would have to meet the outcome requirements for its pediatric and adult transplant centers separately.

If we determine that a transplant center requesting initial approval is in compliance with the proposed data submission and outcome measure

requirements proposed at § 482.80 (based on our review of the data), then we, or our designee, would conduct a site survey of the center to determine compliance with CoPs proposed at § 482.68 through § 482.76 and § 482.90 through § 482.104 using the procedures described at 42 CFR part 488, subpart A. To maximize efficient utilization of resources, the data and outcome requirements would serve as prerequisites that would need to be met based on a desk review of the data before a survey for compliance with the process requirements would be conducted. We propose that centers that failed to meet the data or outcome requirements, including the requirement to have post-transplant follow-up on at least 9 transplants during the reported cohorts, would be denied approval and no survey would be performed.

B. Effective Dates for Initial Approval

Under the current national coverage decisions for heart, liver, and lung transplant centers, Medicare approval of a facility to perform Medicare-covered transplants is effective as of the date of the letter notifying the center of its approval. Under this proposed rule, Medicare approval of all transplant centers to perform Medicare-covered transplants would be effective as of the date of the letter notifying the center of its approval. However, in order to ensure that Medicare-covered transplants are performed only in centers with continued demonstration of experience and skill in a particular type of transplant, we propose limiting a transplant center's approval to 3 years. A time-limited approval would provide us with a mechanism to re-evaluate a transplant center's ability to maintain the skill and experience necessary to perform transplants safely and efficiently.

C. Re-approval Procedures

We propose at § 488.61(b) that transplant centers would be required to comply with the data submission, outcome and process requirements at all times during the 3-year approval period. We may evaluate whether a transplant center is in compliance with the CoPs for transplant centers at any time during the 3-year approval period. For example, if the OPTN notified us that a center failed to meet the proposed data submission requirements, we would consider this significant information that would warrant conducting a complaint investigation.

At least 180 days before the end of a transplant center's 3-year approval period, we would evaluate each center's data for compliance with the data submission and outcome requirements for re-approval proposed at § 482.82, including the requirement to have post-transplant follow-up on at least 9 transplants during the 2.5-year period reported by the SRTR in the most recent center-specific report. For compliance with the data submission requirements, we would review the OPTN's statistics on data completeness for the previous 3 calendar years. For compliance with the outcome measures requirements, we would review the data contained in the most recent SRTR center-specific reports. As stated previously, the SRTR center-specific reports are updated every six months in January and July of each year. If, for example, a transplant center's Medicare approval ends on October 1, 2006, we would review the center's 1-year patient and graft survival statistics from the SRTR's July 2006 reports. As stated previously, the July 2006 SRTR center-specific reports would include patient and graft survival statistics on transplants performed anywhere between 1 to 3.5 years previously.

We propose that if we determine that a transplant center has met the data submission and outcome requirements proposed at § 482.82, including the requirement to have post-transplant follow-up on at least 9 transplants during the 2.5-year period reported by the SRTR in the most recent center-specific report, the transplant center would be re-approved for 3 years. The re-approval dates would vary from center to center based on their initial approval dates. We propose that if, however, we determine that a center has failed to meet the data submission and outcome measure requirements proposed at § 482.82, including the requirement to have post-transplant follow-up on at least 9 transplants during the 2.5-year period reported by the SRTR in the most recent center-specific report, a survey for compliance with the CoPs proposed at § 482.68 through § 482.76 and § 482.90 through § 482.104 would be necessary for a transplant center to be re-approved.

Under some circumstances, we believe that a transplant center's inability to meet the data submission or outcome requirements can be influenced by factors that are not necessarily indicative of the quality of transplantation care. It is possible that a transplant center with a large number of transplant recipients that live outside the transplant center's geographical area might have a difficult time tracking these patients to assess the patients' outcomes or that the center-specific model might fail to take into consideration a significant variable unique to the transplant center. For example, a transplant center may be participating in an institutional review board (IRB) approved immunosuppression withdrawal research protocol that may have resulted in worse than expected graft survival. Therefore, when a center fails to meet the data submission or outcome requirements (including failure to perform at least 9 transplants during the 2.5-year period reported by the SRTR in the most recent center-specific report) based on a desk review of the data, we would also incorporate an onsite survey for compliance with the process requirements. If, based on the survey results, we determine that a center is in compliance with the process requirements, then we would assume that particular center's data submission or outcome data are not necessarily indicative of the quality of transplantation care provided at the center.

As a result, there could be some circumstances under which a center that failed to meet the data submission or outcome requirements would be re-approved. In other words, a successful survey may under certain circumstances make up for a center's failure to meet one or more of the quantitative requirements. We propose that we or our designee would notify the transplant center in writing if it has been re-approved or not. If re-approved, we would also notify the transplant center of the effective date of the re-approval.

D. Alternative Process To Re-Approve Transplant Centers

[If you choose to comment on this issue, please include the caption ''ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS'' at the beginning of your comments.]

We have proposed that transplant centers would be re-approved for 3 years if they met the data submission and outcome requirements proposed at § 482.82. We or our designee would conduct a survey for compliance with the process requirements only if we determined that a center failed to meet the data submission and outcome measures requirements. Nonetheless, we are concerned that adherence to the data submission and outcome measures requirements does not necessarily indicate that a transplant center also is in compliance with the process requirements. For example, a transplant center could have good outcomes but be in violation of our proposed requirements for protection of living donors. Therefore, we have developed an alternative approach for re-approval

of transplant centers that would more closely monitor transplant center compliance with the process requirements. We are requesting comments on this alternative process from the public.

First, as put forth in this proposed rule, we would conduct complaint investigations of transplant centers as needed. In addition, we would conduct random surveys of a certain percentage of centers every year to determine their compliance with the process requirements. Finally, before re-approving centers based on their meeting the data submission and outcome measures requirements, we would determine for each center whether a survey for compliance with the process requirements should be conducted prior to re-approval. We would decide whether to conduct a survey based on information provided to us by the OPTN, such as desk and on-site audit findings and actions taken against a transplant center since the last Medicare approval or re-approval of the center.

We are requesting comments on the feasibility and utility of this option, as well as specific comments regarding: (1) How a random sample should be selected (percentage and type of centers); (2) whether all centers should be surveyed every 3 years, regardless of their compliance with the data submission and outcome requirements; and (3) whether it would be appropriate for CMS to base decisions about the need to conduct individual transplant center surveys on information provided by the OPTN.

E. Loss of Medicare Approval

We propose that centers that have lost their Medicare approval may seek re-entry into the program at any time. Although we are not proposing to restrict when a center can re-enter the Medicare program, we propose that the center must request initial Medicare approval as if it were a new center. In other words, the center would have to request approval using the initial approval procedure described in § 488.61(a). Furthermore, the center would have to be in compliance with all requirements for transplant centers, except for the re-approval requirements at § 482.82, at the time of its request. Regardless of whether the loss of Medicare approval was voluntary or involuntary, we propose that a center seeking to re-enter the Medicare program would have to submit a report documenting any changes or corrective actions the center has taken as a result of the loss of its Medicare approval status.

F. Applications From Consortia

A consortium is a group of hospitals with cooperative arrangements to perform organ transplants. The cooperative arrangements can be formed between a variety of hospitals, such as cooperative arrangements between a university hospital and a Veterans Administration hospital or between hospitals in a given city, state, or region. In most consortia, a single transplant surgeon performs transplants throughout all hospitals in the consortium. Currently, we do not approve consortia collectively as organ transplant centers. However, an individual center that is a member of a consortium may submit an individual application at any time.

We are proposing to retain this policy under the revised requirements because we believe that the extent of a facility's skills and experience can be accurately determined only by looking at each facility on an individual basis; attempting to determine a center's experience level on a consortium basis will not provide the same assurances.

G. Effect of New CoPs for Transplant Centers on Centers That Are Currently Medicare-approved

Since this proposed rule introduces a survey component to the approval procedures for transplant centers, we propose that a hospital that is currently Medicare-approved for furnishing organ-specific transplants would need to request approval for each particular type of transplant center. We propose to treat centers that are currently Medicare-approved as new centers. In other words when this proposed rule is published as a final rule, all transplant centers that are currently Medicare-approved would have to submit a letter of request to CMS for initial Medicare approval if they would like to continue operating as Medicare-approved transplant centers. Transplant centers that are currently Medicare-approved would be expected to meet the data submission outcome, and process requirements contained at § 482.68 through § 482.80 and § 482.90 through § 482.104 when they request Medicare approval.

In order to determine whether or not a center that is currently Medicare-approved is in compliance with the requirements in this proposed rule, we will need to conduct surveys of the transplant center. We propose that transplant centers that are currently Medicare-approved have 180 days from the date these regulations become effective to submit a letter requesting Medicare approval. We, or our designee, would review the center's compliance with the data submission and outcome measure requirements proposed at § 482.80. If we determine that the center that is currently Medicare-approved is in compliance with these quantitative requirements, then we would schedule a survey to determine compliance with the CoPs proposed at §§ 482.68 through 482.76 and §§ 482.90 through 482.104. During the time that the data is reviewed, the survey is conducted and a determination is made, we propose that the transplant centers that are currently Medicare-approved would be able to continue to provide transplant services until we notify them whether or not we have approved them under the new CoPs for transplant centers.

III. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA.

Condition of Participation: Notification to CMS (Section 482.74)

Centers must notify CMS immediately of any significant changes related to the center's transplant program or that would otherwise alter specific elements in their application or re-approval. Several examples are given.

We estimate that the burden associated with this rule will be the time required to notify CMS of significant changes. We estimate that there will be 3 occasions annually per center requiring notification. For each occasion, we estimate that it will take 5

minutes to notify us. Therefore, we believe that it should take no more than 15 minutes annually for each center to notify us of any significant changes such as personnel changes. Assuming that all centers may have significant changes each year, we estimate that there will be approximately 900 centers that will need to inform us of these significant changes for a national total of 225 hours.

Condition of Participation: Pediatric Transplants (Section 482.76)

In order to be reimbursed for pediatric transplants provided to Medicare beneficiaries, a hospital that furnishes transplantation services to pediatric patients must seek Medicare approval to provide pediatric transplantation services. The center must submit a written request for Medicare approval.

We believe that the burden associated with this rule would be the time required to prepare and give us the information. In 2002, there were 75 hospitals that reported performing pediatric heart, heart-lung, intestine, liver, lung, and/or pancreas transplants to the OPTN. Assuming that the number of transplant centers performing pediatric transplants does not fluctuate significantly from year to year and assuming that we can expect all eligible hospitals to apply, we anticipate that there will be 75 hospitals requesting approval under this provision and that it will take each hospital 1 hour per center (*i.e.* a pediatric hospital with a lung center and heart center would require 1 hour to request Medicare-approval for its lung center and 1 hour to request Medicare-approval for its heart center). Since the 75 hospitals performing pediatric transplants have an average of 2 centers, we anticipate the total amount of time required for each hospital to request Medicare-approval will be 2 hours for an one-time national total of 150 hours.

Condition of Participation: Data Submission and Outcome Measure Requirements for Initial Approval of Transplant Centers (Section 482.80)

Except as specified in paragraph (c) of this section, transplant centers must meet all of the data submission requirements in order to be granted approval by CMS. No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants it has performed.

We believe that these requirements reflect usual and customary business practice and would be followed even if there were no Medicare requirements. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

Under certain circumstances, a center may be eligible for initial approval on the basis of its 1-month patient and graft survival rates. In order for CMS to have 1-month patient and graft survival data on all transplants performed during the previous 1-year period, the center may have to submit follow-up data to the SRTR, in addition to the data it normally would submit to the OPTN. The SRTR would need to prepare customized reports based on the 1-month follow-up data. We anticipate that the burden associated with this requirement would be the time required by the transplant centers to submit the necessary data to the OPTN and the time required by the SRTR to prepare the customized reports and submit them to us. However, we do not believe that more than 9 entities will be eligible to be approved on the basis of its 1-month post-transplant outcomes, making this requirement not subject to the PRA, in accordance with 5 CFR 1320.3(c). Between 1998 and 2002, we received and approved applications from an average of approximately 10 heart, intestine, liver, and lung centers each year. We expect that fewer than 10 centers will apply for and be eligible to apply on the basis of their 1-month post-transplant outcomes each year. Furthermore, out of the 239 heart, liver, lung and intestinal transplant centers that are Medicare-approved as of October 20, 2003, only 5 have voluntarily terminated their Medicare approval. We do not expect this requirement to significantly increase the number of centers that voluntarily terminate their Medicare approval.

Condition of Participation: Data Submission and Outcome Measure Requirements for Re-Approval of Transplant Centers (Section 482.82)

Except as specified in paragraph (c) of this section, transplant centers must meet all the data submission and outcome measure standards in order to be re-approved. No later than 90 days after the due dates established by the OPTN, a transplant center must submit to the OPTN 95 percent of the required data submissions on all transplants it has performed over the last 3 years.

We believe that these requirements reflect usual and customary business practice and would be followed even if there were no Medicare requirements. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

Condition of Participation: Patient and Living Donor Selection (Section 482.90)

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waitlist or a patient's suitability for transplant. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

Before a transplant center places a transplant candidate on its waitlist, the candidate's medical record must contain documentation that the candidate's blood type has been determined on at least two separate occasions. When a patient is placed on a center's waitlist or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

The facility must document in the transplant candidate's and living donor's medical record the living donor's suitability for donation.

We believe that these requirements reflect usual and customary business practice and would be followed even if there were no Medicare requirements. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

Condition of Participation: Organ Recovery and Receipt (Section 482.92)

Transplant centers must have written protocols for deceased organ recovery, organ receipt, and living donor transplantation to validate donor-recipient matching of blood types and other vital data.

We believe that these requirements reflect usual and customary business practice and would be followed even if there were no Medicare requirements. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

Condition of Participation: Patient and Living Donor Management (Section 482.94)

Transplant centers must have written patient management policies and patient care planning for the pre-transplant, transplant, and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

The burden associated with these requirements is the time it takes to set forth in writing the required policies and planning. We believe that it is usual

and customary business practice for these entities to write down their policies and planning procedures. Thus, any burden would not be subject to the PRA.

In addition, transplant centers must keep their waitlists up to date, including:

(1) Updating waitlist patients' clinical information, as needed to assess a patient's status if an organ becomes available;

(2) Removing patients from the center's waitlist if a patient receives a transplant or dies, or if there is any other reason why the patient should no longer be placed on a center's waitlist; and

(3) Notifying the OPTN within 24 hours of a patient's removal from the center's waitlist.

Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation.

(1) For each patient who receives an evaluation for placement on a center's waitlist, the center must document in the patient's record that the patient has been informed of his or her transplant status, including notification of:

(i) The patient's placement on the center's waitlist;

(ii) The center's decision not to place the patient on its waitlist; or

(iii) The center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed.

Once a patient is placed on a center's waitlist, the center must document in the patient's record that the patient is notified of:

(1) His or her placement status at least once a year, even if there is no change in the patient's placement status; and

(2) His or her removal from the waitlist for reasons other than transplantation or death within 10 days of the patient's removal from the center's waitlist.

In the case of dialysis patients, transplant centers must document in the patient's record that both the patient and the dialysis facility has been notified of the patient's transplant status or of changes in the patient's transplant status.

In the case of patients admitted for organ transplants, transplant centers must maintain written records of multidisciplinary care planning during the pre-transplant period and multidisciplinary discharge planning for post-transplant care.

The burden associated with this rule is the time required to document all the necessary information. We believe that it will take about 17,971 hours per year for all transplant centers to comply with these documentation requirements.

Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (Section 482.96)

Under this section, a transplant center must develop, implement, and maintain a written comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

As part of this condition, a transplant center must establish a written policy to address and document adverse events that occur during any phase of an organ transplantation case and specifies what the policy must address at a minimum.

The burden associated with this rule is the time required to write the improvement program, including the adverse action policy. We anticipate that this will take 8 hours on a one-time basis. Between 1998 and 2002, we received and approved applications from an average of approximately 10 heart, intestine, liver, and lung centers each year. We do not expect that more than 10 centers will apply for and be accepted per year, so the burden subsequent to the implementation of the final rule will be approximately 80 hours.

Condition of Participation: Human Resources (Section 482.98)

The transplant center must identify to CMS and the OPTN a primary transplant surgeon and a transplant physician with appropriate training and experience to provide transplantation services. The burden associated with this requirement is the time it will take to notify CMS. It is information that will be included in the letter requesting initial approval and will not take any additional time.

Condition of Participation: Organ Procurement (Section 482.100)

Under this section, the transplant center must notify CMS in writing no later than 30 days after the termination of any agreement concerning organ procurement between the hospital and the OPO.

The burden associated with this rule is the time required to notify CMS. We estimate that this will not take more than 15 minutes. However, we also do not believe that more than 9 entities will have to comply with this requirement, making it not subject to the PRA, in accordance with 5 CFR 1320.3(c).

Condition of Participation: Patient and Living Donor Rights (Section 482.102)

Transplant centers must have a written informed transplant patient consent process that informs each patient of:

(1) The evaluation process.

(2) The surgical procedures.

(3) Alternative treatments.

(4) Potential medical or psychosocial risks.

(5) National and transplant center-specific outcomes.

(6) The fact that future health problems related to the transplantation may not be covered by the recipient's insurance, and that the recipient's ability to obtain health, disability, or life insurance may be affected.

(7) Organ donor risk factors that could affect the immediate or future success of the graft or the health of the patient, such as the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor.

(8) His or her right to refuse transplantation.

Transplant centers must also have a written living donor informed consent process that informs the prospective living donor of all aspects of and potential outcomes from living donation. Transplant centers must ensure that the prospective living donor is fully informed about specified subjects.

Transplant centers must notify patients placed on the center's waitlist of information about the center that could impact the patient's ability to receive a transplant should an organ become available:

(1) A transplant center served by a single transplant surgeon or physician must inform patients placed on the center's waitlist of the potential unavailability of the transplant surgeon or physician and whether or not the center has a mechanism to provide an alternative transplant surgeon or transplant physician that meets the hospital's credentialing policies.

(2) At least 30 days before a center's Medicare approval is terminated, either voluntarily or involuntarily, the center must: (a) Inform patients on the center's waitlist of this fact and assist them in transferring to the waitlist of another Medicare-approved transplant center without loss of time on the waitlist; and (b) inform Medicare beneficiaries added to the center's waitlist that Medicare will no longer pay for transplants

performed at the center after the effective date of the center's loss of approval.

The burden associated with this rule is the time required to give the patient/living donor the required information. For each patient on a center's waitlist, we estimate that there will be an average of no more than 2 instances that will require the center to comply with any one of these requirements. We expect an average of 88,211 (81,604 patients on the waitlist + 6,607 living donors) waitlist patients and living donors per year who will have to be notified. Assuming that each notification would take approximately 5 minutes, the total national annual burden would be 14,701 hours.

Special Procedures for Approval and Re-Approval of Organ Transplant Centers (Section 488.61)

Under this section, transplant centers must submit a letter of request to CMS for Medicare approval. The letter, signed by a person authorized to represent the center (for example, a chief executive officer), must include the hospital's Medicare provider I.D. number; name(s) of the designated primary transplant surgeon and primary transplant physician; and a statement from the OPTN that the center has complied with all data submission requirements.

Once this rule is finalized, all transplant centers that are currently Medicare-approved would be required to submit this letter if they wish to retain their Medicare approval. Since many transplant hospitals have more than one transplant center, we would assume that we would receive one letter from the hospital containing the required information for each of the hospital's transplant centers rather than a letter from each transplant center. Currently, there are approximately 230 hospitals with a Medicare-approved transplant center. We assume that all 230 hospitals with centers that are currently Medicare-approved would request approval under the new CoPs for transplant centers. Assuming that each letter would take approximately 15 minutes, the total national burden upon initial implementation of this rule would be approximately 58 hours (230 hospitals × 15 minutes/hospital).

In addition, we receive and approve applications from an average of approximately 10 heart, intestine, liver, and lung centers each year. Assuming that we continue to receive and approve 10 new transplant centers each year subsequent to the implementation of the final rule and that each letter from a transplant center would take approximately 10 minutes, we expect the total annual burden subsequent to implementation of the final rule to be approximately 2 hours.

Finally, we propose that any center that has lost its Medicare approval would have to submit a report documenting any changes or corrective actions taken as a result of the center losing its Medicare approval. This report would be submitted to us along with the letter to request Medicare approval. We do not believe that more than 9 entities will be affected by this requirement making this requirement not subject to the PRA, in accordance with 5 CFR 1320.3(c). Out of 239 heart, liver, lung, and intestine centers that are Medicare-approved currently or previously, only 5 centers have voluntarily terminated their Medicare approval. Transplant centers, like other Medicare providers, have rarely had their Medicare approval status revoked involuntarily.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: John Burke, CMS–3835–P Room C4–26–05, 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: Christopher Martin, CMS Desk Officer, CMS–3835– P, christopher_martin@omb.eop.gov Fax (202) 395–6974.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in that document.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980 Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibilities of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate the overall economic impact of this rule to be $300,148; therefore, we do not believe this would be a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations, government agencies, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of $29 million or less in any 1 year (65 FR 69432). Individuals and States are not included in the definition of a small entity. We believe this rule would not have a significant impact on a substantial number of small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We believe this proposed rule would not have a significant impact on small rural hospitals since small rural hospitals do not have the resources to perform organ transplants.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any

rule that may result in expenditure in any 1 year by State, local or tribal governments, in the aggregate, or by the private sector, of $110 million. We do not believe that this rule will have an effect on State, local or tribal governments, or the private sector, that could create an unfunded mandate greater than $110 million annually.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose substantial direct requirement costs on State or local governments and does not preempt State law or have other Federalism implications. We have determined that this notice of proposed rulemaking would not significantly affect the rights, roles, and responsibilities of States.

This proposed rule would affect all facilities that perform, or are planning to perform, organ transplants and may have an effect on the ability of those facilities to compete. Although we do not believe this rule will have a significant impact on small rural hospitals or a significant economic impact, to the extent the rule may have significant effects on beneficiaries, or be viewed as controversial, we believe it is desirable to inform the public of our projections of the likely effects of the proposed rule. Thus, we have prepared the following analysis, which, in combination with the other sections of this proposed rule, is intended to conform to the objectives of the RFA and section 1102(b) of the Act.

B. Anticipated Effects

1. Effects on Transplant Hospitals or Centers

Our intent in developing and implementing the proposed conditions of participation for transplant centers is to ensure Medicare-covered transplants are performed in an efficient manner in keeping with the importance of this scarce resource for individuals on organ transplant waitlists. This proposed regulation also serves to keep Medicare requirements current with the state of the art in transplantation. We do not anticipate that changes in the performance standards for transplant centers would affect the number of transplants performed.

This proposed rule would establish conditions of participation for transplant centers that perform organ transplants. The proposed rule would maintain many of the same requirements that are in the current **Federal Register** notices for heart, lung and liver transplants; National Coverage Policies for pancreas, intestinal and multivisceral transplants, and conditions for coverage for kidney transplant centers. Some of the proposed changes could result in additional costs for some centers. While we do not believe the requirements in this proposed rule would have a substantial economic impact on a significant number of transplant centers, we believe it is desirable to inform the public of our projections of the likely effects of the proposed rule. There are two reasons this proposed rule would have a minimal economic effect.

First, nearly 900 transplant centers may potentially be affected by the requirements in this proposed rule to a greater or lesser degree. However, the majority of the transplant centers probably have already put into practice most of the process requirements we are proposing, because the proposed requirements, for the most part, merely reflect advances in transplantation technology, as well as standard care practices.

Second, although the proposed rule requires a large amount of data to be submitted, transplant centers already submit these data to the OPTN.

a. OPTN Membership

We do not believe there would be any economic impact as a result of our proposal requiring transplant centers to be in a transplant hospital that is member of the OPTN and that abides by OPTN's approved rules and requirements. By statute and under regulations at § 482.45(b)(1) of this chapter, Medicare-approved transplant centers are already required to be in hospitals that are members of the OPTN and that abide by the OPTN's approved rules and requirements.

b. Notice of Significant Changes to CMS

Current Medicare transplant policies require centers to report immediately to CMS any events or changes that would affect their approved status. Specifically, a center is required to report, within a reasonable period of time, any significant decrease in its experience level or survival rates, the departure of key members of the transplant team or any other major changes that could affect the performance of transplants at the center. The proposed standard for notification of significant changes to CMS is almost identical to the current requirements. We do not anticipate any additional economic impact associated with this requirement.

c. Pediatric Transplants

We have proposed to treat centers that perform pediatric transplants like any other transplant center seeking Medicare approval. In addition, we proposed to give heart centers the option of meeting the current requirements for Medicare approval to perform pediatric heart transplants. Hence, we believe the proposed requirements for pediatric transplant centers will result in the same economic impact that centers requesting Medicare approval to perform adult transplants would face when meeting the requirements of this proposed rule. The requirements for pediatric transplants alone would not be an economic burden.

d. Data Submission

The proposed data submission requirements for initial approval and re-approval require a transplant center to submit to the OPTN, no later than 90 days after the due date established by the OPTN, at least 95 percent of required data submissions on all transplants it has performed. We believe there would be little or no economic impact since the proposed requirements essentially mirror the OPTN's policies on data submission. We anticipate that most transplant centers are already submitting data to the OPTN as part of their membership responsibilities.

e. Outcome Measures

Currently, heart, liver and lung centers are required to calculate and report 1-year and 2-year actuarial survival analysis using the modified Kaplan-Meier technique. We propose shifting all the calculation and analysis responsibilities from the centers to the SRTR, which currently uses the OPTN data to prepare both center-specific and national statistical reports. We have proposed utilizing the SRTR center-specific reports to evaluate transplant center outcomes. Therefore, we believe there would be no or little economic impact on transplant centers as a result of this proposed requirement, unless one of the conditions in which a center may request Medicare approval on the basis of its 1-month post-transplant outcomes applies. In this case, there would be minimal economic burden associated with submitting follow-up data to the SRTR. There will be a cost of approximately $1,000 to generate a customized report from the SRTR for 1-month post-transplant data. However, transplant centers have the option of waiting until their 1-year post-transplant data is available as part of the

center-specific reports if they do not wish to incur this cost.

f. Patient and Living Donor Selection

Under current policies, centers must have adequate written patient selection criteria and medical criteria for heart, liver and lung transplants, and clinical indications for coverage for pancreas and intestinal transplants. We propose similar patient selection requirements under the proposed condition and we believe there would be little or no economic impact from this condition.

In addition to the proposed patient selection criteria, we are also proposing to require written living donor selection criteria and a psychosocial and medical evaluation for living donors. Given the potential risks to living donors, we believe that every hospital that performs living donor transplants has protocols for the selection of living donors that include procedures for performing a medical and psychosocial evaluation of the donor. Therefore, the condition proposed here would only affect those few transplant centers performing living donor transplants that do not already have written donor selection criteria.

g. Organ Recovery and Receipt

The proposed condition for organ recovery and receipt requires transplant centers to have protocols for organ recovery and receipt that include protocols for validating the donor-recipient match. We believe nearly all transplant centers already have these protocols. We also believe that most transplant centers follow these practices to some degree. The proposed condition for organ recovery and receipt also assigns responsibility for ensuring the medical suitability of donor organs for transplantation into the intended recipient to the transplanting surgeon. We believe that most transplant centers currently follow this practice. Therefore, we foresee only minimal economic impact from the proposed requirements.

h. Patient and Living Donor Management

Some of the requirements proposed in this condition require transplant centers to have patient and living donor management policies during all phases of transplantation or living donation and this would have some economic impact on centers. We are proposing a waitlist management requirement for transplant centers to keep their waitlist current with patients' clinical data and information regarding patients' removal from the waitlist. The requirement also stipulates timely notification of patients' removal to the OPTN. Updating the OPTN of a patient's removal from the center's waitlist and updating the waitlist patients' clinical information on an ongoing basis are best practices that transplant centers use to assess transplant suitability should an organ become available. We do not anticipate additional economic impact associated with this requirement.

We propose a patient records requirement for transplant centers to maintain current and accurate management records for each patient who is evaluated for placement on the center's waitlist and is admitted for organ transplantation. Specifically, we propose that once a patient has received an evaluation for transplant, a transplant center is required to document that it has notified the patient when: (1) The patient is placed on the center's waitlist; (2) the center decides not to place the patient on its waitlist; or (3) the transplant center requires further clinical testing or documentation before determining whether the patient can be placed on the center's waitlist. We also propose that once a patient is placed on a center's waitlist, the center must notify the patient of his or her removal from the waitlist for reasons other than transplantation or death no later than 10 days after the patient's removal from the center's waitlist and document that the patient has been notified in the patient's record. These proposed patient notification and documentation requirements are based on the OPTN requirements.

The currently, the OPTN requires transplant centers to notify patients of their status in writing (1) within 10 business days of the patient's placement on the OPTN Patient Waitlist or if a determination has been made based on evaluation of the patient that the patient will not be placed on the OPTN waitlist at this time and (2) within 10 business days of removal from the OPTN Patient Waitlist for reasons other than transplant. We expect that most transplant centers are currently in compliance with this OPTN requirement. We also believe that our proposed requirements provide transplant centers with more flexibility to determine how to notify patients than the current OPTN requirements. Therefore, we do not believe that transplant centers would incur any additional economic impact as a result of this proposed rule.

We are also proposing to require that once a patient has been placed on a center's waitlist, the center must document in the patient's record that the center has informed the patient of his or her status at least once a year, even if there is no change in status. Furthermore, for patients on dialysis, the patient's record must also include documentation that the patient's usual dialysis facility is also notified of a patient's transplant status and of changes in the patient's transplant status. We anticipate this requirement would result in some economic impact on transplant centers. As of December 31, 2003, there were 83,731 waitlist registrations on the OPTN waitlist for deceased organs, which was a 5.5 percent increase from 79,387 registrations at the end of 2002 (2003 SRTR Annual Report). Assuming that, on average, the number of registrations on the OPTN waitlist for deceased organs increases by 6 percent each year, we can expect that by the end of 2006, there will be 99,725 registrations on the OPTN waitlist for deceased organs. Since transplant centers vary by size, it is not possible to determine a mean number of patients that each center lists on the OPTN waitlist. Thus, in quantifying the burden of notifying patients of their status annually, we are assuming that every transplant center that is a member of the OPTN either has Medicare approval or applies for Medicare approval as a transplant center as a result of this proposed rule. Consequently, assuming that it will take administrative support personnel, at an average salary of $12 per hour, no more than 10 minutes to provide each patient on the deceased organ waitlist written notification of their status then the total maximum annual labor hours to all transplant centers is expected to be 16,621 hours (99,725 patient notifications × 10 minutes for notification) and the total maximum annual labor cost to all transplant centers in the U.S. is expected to be $199,452 (16,621 hours × $12/hour) in 2006. In addition, we estimate the total cost of the paper, envelopes, toner, and postage required to produce and mail each letter would be $49,863 (99,725 patient notifications × $0.50/notification). Therefore, the total estimated cost of notifying patients annually of their waitlist status is $249,315 ($199,452 + $49,863), if we assume that transplant centers choose to notify patients in writing.

We assume that in order to notify a dialysis facility of a patient's status, the transplant center would just send the dialysis facility a copy of the letter notifying the patient of his or her status. We estimate that the 99,725 OPTN waitlist registrations expected by the end of 2006 would include 64,203 registrations on the OPTN kidney waitlist and 3,062 registrations on the OPTN kidney-pancreas waitlist if we assume that the 6 percent annual growth

rate for all transplants applies to kidney transplants and kidney-pancreas transplants. Therefore, transplant centers would need to notify dialysis facilities of the status of 67,265 patients. Since we are assuming that transplant centers would notify patients in writing and just send dialysis facilities a copy of the letter to the patient notifying the patient of his or her status, we estimate that it will take administrative support personnel, at an average salary of $12 per hour, approximately 1 minute per letter to print a copy for the dialysis facility. Consequently, the total estimated annual labor burden for all transplant centers to notify dialysis facilities of patient status is approximately 1,121 hours (67,265 dialysis facility notifications × 1 minute/notification) and the total estimated labor costs for all transplant centers to notify dialysis facilities of patient status is approximately $13,452 (1,121 hours × $12/hour). The total cost of the paper, toner, and postage required to produce and mail each letter is estimated to be $33,633 (67,265 dialysis facility notifications × $0.50/notification). Therefore, we estimate the total cost of mailing notification letters to the dialysis facility to be $47,085 and the total cost of notifying both patients and dialysis facilities to be $296,400 ($47,085 for notifying dialysis facilities annually + $249,315 for notifying patients annually).

PROJECTED NUMBER OF WAITING LIST PATIENTS

Calendar year	Number of patients on:		
	OPTN waiting list (all transplants)	Kidney waiting list	Kidney-pancreas waiting list
2003	83,731	53,906	2,571
2004	88,755	57,141	2,725
2005	94,080	60,569	2,888
2006	99,725	64,203	3,062

CALENDAR YEAR 2003 COST ESTIMATES

Requirement	Calculations	Annual burden hours	Annual cost estimate
Annual notification of patient status to patients	99,725 patients on OPTN waiting list × 10 min./written notification.	16,621	
	1 admin. support staff × $12/h × 16,621 h		$199,452
	99,725 notifications × $0.50/notification		$49,863
Total for annual notification to patients		16,621	$249,315
Annual notification of patient status to dialysis centers.	67,265 patients on OPTN waiting list for kidney or kidney-pancreas transplant × 1 min./written notification.	1,121	
	1 admin. support staff × $12/h × 1,121		$13,452
	67,265 dialysis facility notifications × 0.50/notification		$33,633
Total for annual notification to dialysis facilities.		1,121	$47,085
Annual Total For Both Requirements		17,742	$296,400

For patients admitted for organ transplants, we expect that documentation of pre-transplant multidisciplinary patient care planning and post-transplant discharge planning are common practices for most transplant centers. Therefore, there will be little resultant economic impact.

We are proposing to require every center to make available a qualified social worker to provide psychosocial supportive services to transplant patients, living donors, and their families. We are also proposing to require every center to make available a qualified dietitian to provide nutritional assessments and diet counseling to all transplant patients and living donors. Current policies for heart, liver and lung transplants require facility commitment at all levels, including social service resources. We believe nearly all transplant centers already have a qualified social worker and a dietitian to provide psychosocial, supportive, and nutrition services. Thus, most centers would not need to hire any additional staff to meet this requirement. Therefore, there will be little resultant economic impact.

i. QAPI

The condition for QAPI will have some economic impact on the minority of centers that do not have a data-driven QAPI program. We estimate that a center that does not currently have a QAPI program probably would need one professional position to develop, implement, and coordinate a program that reflects the scope and complexity of the center's transplant program. We imagine a center would likely utilize an experienced individual from its hospital QAPI staff. QAPI coordinators are usually registered nurses (RNs) and sometimes individuals with other backgrounds. In 2002, the mean annual income of an RN was $42,730. We request comments addressing whether transplant centers would be able to utilize individuals from the hospital's existing QAPI staff to develop and implement a QAPI program specific to the transplant center or whether transplant centers would need to hire additional staff in order to comply with this proposed requirement.

j. Human Resources

The condition for human resources would require every center to designate a qualified director to provide general supervision over the center and to designate a primary transplant surgeon and physician with the appropriate training and experience to provide transplantation services. The director of the transplant center would not need to serve full time and may also serve as the center's primary transplant physician. Therefore, the primary transplant

surgeon and the physician could be the same individual, if necessary. The kidney transplant regulations require renal transplant centers to be supervised by a qualified transplantation surgeon or qualified physician-director. Current transplant center criteria require a transplant center to be a member of the OPTN and abide by its rules. The OPTN requires its members to have transplant surgeons and physicians with specific qualifications, training and experience. We believe all transplant centers already have designated primary transplant surgeons and transplant physicians. We also believe that in most transplant centers the primary transplant surgeon or transplant physician provides general supervision over the transplant center. Therefore, we do not believe this condition would have a significant economic impact.

We are also proposing to require every center to have a clinical transplant coordinator. Because of the complex medical needs of post-transplant patients and living donors, we believe, it is crucial for every center to have a clinical transplant coordinator. We believe most centers have a clinical transplant coordinator on staff to coordinate all patient care and management activities. Clinical transplant coordinators are usually registered nurses (RNs). According to the Bureau of Labor Statistics, the 2002 mean annual income of an RN was $42,730.

Like the current policies for heart, liver and lung transplants, the human resources condition also would require centers to have a stable transplant team with delineated responsibilities for its members. The team must be composed of individuals with appropriate qualifications, training, and experience in relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology. Since transplant centers and transplant hospitals are usually staffed with such individuals, we believe this requirement would not have a significant economic impact on transplant centers. Also, we propose that transplant centers must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease, pathology, radiology, and blood banking as related to the provision of transplantation services. We expect these are integral parts of transplantation services. Therefore, this requirement would not have resultant economic impact.

k. Organ Procurement

We propose requiring transplant hospitals to have a written agreement for the receipt of organs with an OPO designated by the Secretary. The transplant hospital-OPO agreement would have to identify specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation. Under § 482.45, all Medicare participating hospitals already have such written agreements with an OPO in their service areas. There is no additional economic impact associated with this condition.

l. Patients' and Living Donors' Rights

Current kidney transplant regulations require a center to inform patients regarding their suitability for transplantation. The OPTN states that patients must be informed of their rights in advance of transplantation. The proposed condition for patients and living donors' rights would require every transplant center to inform patients and living donors of their rights in advance of transplantation or donation and to provide written informed consent to patients and living donors. The proposed condition requires centers to inform patients of donor history, the use of marginal organs or organs from donors who are at risk for HIV and other infectious diseases. We also propose requiring centers to inform patients of all aspects of and potential outcomes from transplantation, such as the evaluation process, the surgical procedure, alternative treatments for the transplant patient, potential medical and psychosocial risks to the patient, specific transplant outcomes for recipients, and their right to refuse transplantation. Furthermore, the proposed standard requires centers to provide information to prospective living donors regarding all aspects of and potential outcomes from living donation, such as the evaluation process, surgical procedure, alternative treatments for the transplant patient, potential medical and psychosocial risks to the donor, specific transplant outcomes for both donors and recipients, and potential future health and life insurance coverage problems related to living donation. The proposed standard also requires centers to give potential living donors the option to refuse donation at any time during the donation process. We believe all transplant centers have policies for an informed consent process for patients. Under the proposed condition, some centers may have to broaden their informed consent policies to include living donors. However, these provisions would have little resultant economic impact.

Furthermore, the condition also requires centers with a single transplant team to inform patients of the potential unavailability of the transplant team should an organ become available for the patient and whether or not the transplant center has a mechanism to provide an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies should the center's transplant surgeon or physician be unavailable. We also propose that at least 30 days before a center's Medicare approval is terminated, the center must inform patients on the center's waitlist of this fact immediately and provide assistance to waitlist patients who choose to transfer to the waitlist of another Medicare-approved center and inform Medicare beneficiaries added to the center's waitlist that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination. We believe that any additional economic impact from this requirement would be minimal because current OPTN requirements require transplant centers that are inactive, either voluntarily or involuntarily, to notify patients and to assist them in transferring to a waitlist of an active center. The OPTN requirements also allow the patient to retain his or her waiting time.

m. Additional Requirements for Kidney Transplant Centers

Current kidney transplant regulations require ESRD facilities such as kidney transplant centers to participate in ESRD network activities for ESRD program administration. Therefore, we do not expect these requirements to have any resultant economic impact.

2. Effects on the Rights of Patients and Living Donors

The patients' and living donors' rights proposed in this rule are designed to increase the focus on patient and living donor transplantation choices. We believe we have strengthened a number of patient protections and have reinforced our mandate to protect the health, safety, and welfare of patients served.

3. Effects on the Medicare Program

Although the number of organ transplants has grown rapidly, donor availability is a significant limitation on the number of transplants that are performed. Because of their age and the presence of other complicating conditions, only a relatively small number of Medicare beneficiaries are presently heart, heart-lung, liver, lung, intestinal, or pancreas transplant

candidates. For example, while Medicare covered 12,721 kidney transplants in 2002, only 515 heart transplants, 779 liver transplants, 209 lung transplants, 6 heart-lung transplants, and 693 pancreas transplants were covered by Medicare. It is difficult to precisely estimate future Medicare costs, largely due to the difficulty of predicting the availability of donor organs over the next few years. All dollar estimates depend on assumptions and estimates related to the number of covered transplants. Based on the Office of the Actuary's 5-year budget projections, we consider future changes in organ transplant cost estimates over time to be negligible, and therefore we believe that this regulation will have no significant dollar impact. If anything, the CoPs could save Medicare dollars by improving patient care (preventing morbidity that would result in re-hospitalization) and preventing some graft failure (which would obviate the need for re-transplantation) or a return to dialysis for kidney patients. In addition, we do not believe this rule will increase the number of Medicare-covered transplants performed since there is nothing in the rule that impacts donation or the allocation of organs.

We propose procedures for approval and re-approval of transplant centers at § 488.61. For initial approval, we propose that all the CoPs proposed at § 482.68 through § 482.104, except for § 482.82 (Re-approval requirements), would have to be met in order for a transplant center to become Medicare-approved. Determinations on whether or not a transplant center is in compliance with these requirements would be made based on a review of a transplant center's data submission and outcome measures data required at § 482.80 and on the results of a survey for compliance with proposed § 482.68 through § 482.76 and § 482.90 through § 482.104, using the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A.

We propose to re-approve transplant centers every 3 years, but transplant centers would need to be in compliance with CoPs at § 482.68 through § 482.76 and § 482.82 through § 482.104 at all times. At least 180 days prior to the end of a transplant center's 3-year approval period, we would review the transplant center's data submission and outcome measures data. We propose that if we, or our designee, determine that a transplant center has met the data submission or outcome requirements proposed at § 482.82, the transplant center would be approved for 3 years. If we, or our designee, determine that the transplant center has failed to meet the data submission and outcome measure requirements at § 482.82, the transplant center would be surveyed for compliance with § 482.68 through § 482.76 and § 482.90 through § 482.104 using the procedures described at 42 CFR part 488, subpart A. We propose that transplant centers which have lost their Medicare approval would have to apply for initial approval as if they were a new center to re-enter the Medicare program and submit a report documenting any changes and/or corrective actions that have been made as a result of the loss of the center's Medicare approval status. We believe that such documentation would be a customary business practice that would be part of the center and/or hospital's QAPI program.

We believe that the proposed procedures for approval and re-approval will have some economic impact on the Medicare program since transplant centers may need to be surveyed more frequently. We believe most of the economic impact on the Medicare program associated with the proposed approval and re-approval procedures would occur during initial implementation. We propose to treat centers that are currently Medicare-approved as new centers that would need to submit a letter of request to CMS for initial Medicare approval and meet the requirements for initial approval. Therefore, we, or our designee, would need to survey all the centers that are currently Medicare-approved that meet the data submission and outcome measure requirements proposed at § 482.80 when this proposed rule goes into effect. We propose that all transplant centers that are currently Medicare-approved and that wish to continue to be Medicare-approved under the new CoPs for transplant centers would have 180 days from the date these regulations become effective to submit a letter requesting Medicare approval. Based on the number of request letters we receive during these initial 180 days, we would schedule the survey of these transplant centers in a manner that would allow the surveyor(s) to survey all the transplant centers requesting approval within a particular hospital during the same visit. To further minimize burden on the Medicare program, we also propose that during the time the data are reviewed, the survey is conducted, and a determination made, transplant centers that are currently Medicare-approved would be able to continue to provide transplant services until we notify them whether or not we have approved them under the new CoPs for transplant centers.

Currently, there are approximately 250 transplant hospitals that are members of the OPTN. About 93 percent of these transplant hospitals have at least one Medicare-approved transplant center. Assuming that all the transplant centers that are currently Medicare-approved request approval under the new CoPs and meet the data submission and outcome requirements proposed at § 482.80, we would need to survey approximately 230 hospitals. Since the transplant centers would be able to continue to provide transplantation services until we notify them of their approval status under the new CoPs, we plan to stagger surveys of these hospitals over time. Therefore, we do not believe there would be a significant economic impact as a result of our proposal to treat all centers that are currently Medicare-approved as new centers.

C. Conclusion

We believe that the criteria we have developed are the most effective means available to ensure that organ transplants made available to patients are provided in a safe and effective manner. We estimate the net cost of this proposed rule to be approximately $300,000. We do not believe that any transplant hospitals are small rural hospitals within the definition of the Social Security Act. Although some transplant hospitals are small entities by virtue of their non-profit status, few if any of them will have any consequential cost. For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals or on other small entities.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget (OMB).

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 482

Grant programs-health, Hospitals, Medicare, reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart U—Conditions for Coverage of End-Stage Renal Disease (ESRD) Services

1. The authority citation for Part 405, Subpart U continues to read as follows:

Authority: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b-8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

§§ 405.2120 through 405.2134 and 405.2170 through 405.2171 [Removed]

2. Sections 405.2120 through 405.2134 and 405.2170 through 405.2171 are removed.

§ 405.2102 [Amended]

3. Section 405.2102 is amended by—

A. Removing the definitions for ''histocompatibility testing,'' ''Network, ESRD,'' ''Network organization,'' and ''organ procurement''.

B. Amending the definition of ''ESRD facility'' by removing paragraph (a) and by redesignating paragraphs (b) through (e) as paragraphs (a) through (d).

C. Amending the definition of ''ESRD service'' by removing paragraph (a) and by redesignating paragraphs (b) and (c) as paragraphs (a) and (b).

D. Amending the definition of ''Qualified personnel'' by removing paragraph (g).

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 is revised to read as follows:

Authority: Secs.1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395RR), unless otherwise noted.

2. Part 482 is amended by revising subpart E to read as follows:

Subpart E—Requirements for Specialty Hospitals

Sec.

482.68 Special Requirements for Transplant Centers.
482.70 Definitions.

General Requirements for Transplant Centers

482.72 Condition of participation: OPTN membership.
482.74 Condition of participation: Notification to CMS.
482.76 Condition of participation: Pediatric Transplants.

Transplant Center Data Submission and Outcome Requirements

482.80 Condition of participation: Data submission and outcome measure requirements for initial approval of transplant centers.
482.82 Condition of participation: Data submission and outcome measure requirements for re-approval of transplant centers.

Transplant Center Process Requirements

482.90 Condition of participation: Patient and living donor selection.
482.92 Condition of participation: Organ recovery and receipt.
482.94 Condition of participation: Patient and living donor management.
482.96 Condition of participation: Quality assessment and performance improvement (QAPI).
482.98 Condition of participation: Human resources.
482.100 Condition of participation: Organ procurement.
482.102 Condition of participation: Patient and living donor rights.
482.104 Condition of participation: Additional requirements for kidney transplant centers.

Subpart E—Requirements for Specialty Hospitals

§ 482.68 Special requirements for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in § 482.70 through § 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at § 482.70 through § 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in § 482.70 through § 482.104, a transplant center must also meet the conditions of participation specified in § 482.1 through § 482.57.

§ 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include living donor death due to mismanagement of the donor; transplantation of organs of mismatched blood types due to failure to validate the donor and recipient's vital information; transplantation of organs to unintended recipients; avoidable loss of a healthy living donor; and unintended transmission of infectious disease to a recipient.

End-Stage Renal Disease (ESRD) means that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Network means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Heart-lung transplant center means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

Intestinal transplant center means a Medicare-approved liver transplant center that performs intestinal transplants, combined liver-intestinal transplants, or multivisceral transplants.

Network organization means the administrative governing body to the network and liaison to the Federal government.

Pancreas transplant center means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

Transplant center means an organ-specific transplant program within a transplant hospital (*i.e.*, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant program means a component within a transplant hospital that provides transplantation of a particular type of organ.

General Requirements for Transplant Centers

§ 482.72 Condition of participation: OPTN membership.

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term ''rules and requirements of the OPTN'' means those

rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No transplant hospital shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

§ 482.74 Condition of participation: Notification to CMS.

A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that would otherwise alter specific elements in their application for approval or re-approval. Instances in which CMS should be notified include, but are not limited to:

(a) Change in key staff members of the transplant team, such as a change in the individual the transplant center designates to the OPTN as the center's ''primary transplant surgeon'' or ''primary transplant physician;'' or

(b) A decrease in the center's volume or survival rates that could result in the center being out of compliance with § 482.82.

§ 482.76 Condition of participation: Pediatric Transplants.

A transplant center that wishes to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described in § 488.61.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation contained in § 482.68 through § 482.74 and § 482.80 through § 482.104 with respect to its pediatric patients.

(b) A center that performs 50 percent or more of its transplants on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform pediatric transplants.

(2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, will not impact the center's Medicare approval to perform adult transplants.

(c) A center that performs 50 percent or more of its transplants on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

(1) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform adult transplants.

(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will not impact the center's Medicare approval to perform pediatric transplants.

(3) No minimum number of transplants (adult or pediatric) is required prior to approval.

(d) Instead of meeting all of the conditions of participation contained in § 482.68 through § 482.74 and § 482.80 through § 482.104, a heart transplant center that wishes to provide transplantation services to pediatric heart patients, may be approved to perform pediatric heart transplants by meeting the following criteria:

(1) The center's pediatric transplant program must be operated jointly by the center and another facility that is Medicare-approved;

(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

(3) The center demonstrates to the satisfaction of the Secretary that it is able to provide specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

Transplant Center Data Submission and Outcome Requirements

§ 482.80 Condition of participation: Data submission and outcome requirements for initial approval of transplant centers.

Except as specified in paragraph (c) of this section, transplant centers must meet all of the data submission and outcome measure standards in order to be granted initial approval by CMS. No waivers will be granted to centers that have failed to meet any one of the standards:

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration, and recipient follow-up.

(b) *Standard: Outcome measures.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) center-specific report, as long as the center has 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type.

(2) The 9 transplants must have been performed during the timeframe reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rate to be acceptable if:

(i) A center's observed patient survival rate and observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05, (B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(4) A center may request that CMS review its 1-month patient and graft survival outcomes for all transplants performed in the previous 1-year period in lieu of 1-year patient and graft survival outcomes if the following conditions are met:

(i) The key members of the center's transplant team performed transplants at a Medicare-approved transplant center for a minimum of 1 year prior to the opening of the new center and the transplant center's team meets the human resources requirements at § 482.98., and

(ii) The most recent SRTR center-specific report does not contain 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type that were performed during the timeframe reported in the most recent SRTR center-specific report

(5) A center that chooses to request initial Medicare approval using its 1-month patient and graft survival outcomes must:

(i) Request the SRTR to calculate the center's observed and expected 1-month

patient and graft survival outcomes for transplants performed during the previous one-year period; and

(ii) Have 1-month post-transplant follow-up on at least 9 transplants of the appropriate organ type that were performed during the previous one-year period.

(6) When assessing a center's 1-month post-transplant outcomes, CMS will compare each transplant center's observed number of patient deaths and graft failures 1-month post-transplant to the center's expected number of patient deaths and graft failures 1-month post-transplant using the methodology described in § 482.80(b)(3).

(c) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the outcome measure requirements at § 482.80(b) for heart-lung transplants performed at the center.

(2) An intestinal transplant center is not required to comply with the outcome performance measure requirements at § 482.80(b) for intestinal, combined liver-intestinal or multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the outcome measure requirements at § 482.80(b) for pancreas transplants performed at the center.

(4) A center that is requesting initial Medicare approval to perform pediatric transplants is not required to perform a minimum number of pediatric transplants prior to its request for approval.

§ 482.82 Condition of participation: Data submission and outcome requirements for re-approval of transplant centers.

Except as specified in paragraph (c) of this section, transplant centers must meet all data submission and outcome measure standards in order to be re-approved.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration, and recipient follow-up.

(b) *Standard: Outcome measures.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent SRTR center-specific report, as long as the center has 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type.

(2) The 9 transplants must have been performed during the timeframe reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rate to be acceptable if:

(i) A center's observed patient survival rate and observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and

(ii) All three of the following thresholds are crossed:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(c) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the outcome measure requirements at § 482.82(b) for heart-lung transplants performed at the center.

(2) An intestinal transplant center is not required to comply with the outcome measure requirements at § 482.82(b) for intestinal, combined liver-intestinal and multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the outcome measure requirements at § 482.82(b) for pancreas and kidney-pancreas transplants performed at the center.

(4) A center that is approved to perform pediatric transplants is not required to perform a minimum number of pediatric transplants to be re-approved.

Transplant Center Process Requirements

§ 482.90 Condition of participation: Patient and living donor selection.

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waitlist or a patient's suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

(a) *Standard: Patient selection.* Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

(1) Before a patient is selected for transplant, except for kidney transplant patients, the transplant center must employ or consider all other appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplantation.

(2) Prior to placement on the center's waitlist, a prospective transplant candidate must receive a psychosocial evaluation.

(3) Before a transplant center places a transplant candidate on its waitlist, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

(4) When a patient is placed on a center's waitlist or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

(b) *Standard: Living donor selection.* The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

(2) Document in the transplant candidate's and living donor's medical records the living donor's suitability for donation, and

(3) Document that the living donor has given informed consent, as required under § 482.102.

§ 482.92 Condition of participation: Organ recovery and receipt.

Transplant centers must have written protocols for deceased organ recovery, organ receipt, and living donor transplantation to validate donor-recipient matching of blood types and other vital data. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

(a) *Standard: Organ recovery.* A transplant center's organ recovery team must review and compare the donor-data with the recipient blood type and other vital data before organ recovery takes places.

(b) *Standard: Organ receipt.* When an organ arrives at the center, the

transplanting surgeon and at least one other individual at the transplant center must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient prior to transplantation.

(c) *Standard: Living donor transplantation.* If a center performs living donor transplants, the transplanting surgeon and at least one other individual at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

§ 482.94 Condition of participation: Patient and living donor management.

Transplant centers must have written patient management policies for the pre-transplant, transplant, and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

(a) *Standard: Patient and living donor care.* The transplant center's patient and donor management policies must ensure that:

(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the pre-transplant, transplant, and discharge phases of transplantation; and

(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

(b) *Standard: Waitlist management.* Transplant centers must keep their waitlists up to date, including:

(1) Updating of waitlist patients' clinical information on an ongoing basis;

(2) Removing patients from the center's waitlist if a patient receives a transplant or dies, or if there is any other reason why the patient should no longer be on a center's waitlist; and

(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waitlist.

(c) *Standard: Patient records.* Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation.

(1) For each patient who receives an evaluation for placement on a center's waitlist, the center must document in the patient's record that the patient is informed of his or her transplant status, including notification of:

(i) The patient's placement on the center's waitlist;

(ii) The center's decision not to place the patient on its waitlist; or

(iii) The center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed.

(2) Once a patient is placed on a center's waitlist, the center must document in the patient's record that the patient is notified of:

(i) His or her placement status at least once a year, even if there is no change in the patient's placement status; and

(ii) His or her removal from the waitlist for reasons other than transplantation or death no later than 10 days after the patient's removal from the center's waitlist.

(3) In the case of dialysis patients, transplant centers must document in the patient's record that both the patient and the patient's usual dialysis facility have been notified of the patient's transplant status and any changes in the patient's transplant status.

(4) In the case of patients admitted for organ transplants, transplant centers must maintain written records of:

(i) Multidisciplinary patient care planning during the pre-transplant period; and

(ii) Multidisciplinary discharge planning for post-transplant care.

(d) *Standard: Social services.* The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 482.94(d)(1).

(e) *Standard: Nutritional services.* Transplant centers must make nutritional assessments and diet counseling services furnished by a qualified dietitian available to all transplant patients and living donors. A qualified dietitian is an individual who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Activities and outcomes may include, but are not limited to, patient and donor selection criteria, accuracy of waitlist in accordance with the OPTN waitlist, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient satisfaction and patient rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Adverse events.* A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

(1) The policies must address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events.

(2) The transplant center must conduct a thorough analysis of and document any adverse event and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.

§ 482.98 Condition of participation: Human resources.

The transplant center must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

(a) *Standard: Director of a transplant center.* The transplant center must be under the general supervision of a qualified transplant surgeon or a

qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with § 482.98(b).

This director is responsible for planning, organizing, conducting and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:

(1) Ensuring adequate training of nursing staff in the care of transplant patients.

(2) Ensuring tissue typing and organ procurement services are available.

(3) Ensuring that transplantation surgery is performed under the direct supervision of a qualified transplant surgeon in accordance with § 482.98(b).

(b) *Standard: Transplant surgeon and physician.* The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services.

(1) The transplant surgeon is responsible for providing surgical services related to transplantation.

(2) The transplant physician is responsible for providing and coordinating transplantation care.

(c) *Standard: Clinical transplant coordinator.* The transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. A qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators.

(d) *Standard: Transplant team.* The transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

(e) *Standard: Resource commitment.* The transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, and blood banking as related to the provision of transplantation services.

§ 482.100 Condition of participation: Organ procurement.

The transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary.

(a) The transplant center must ensure that the hospital's agreement with the OPO identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

(b) The transplant center must notify CMS in writing no later than 30 days after the termination of any agreement between the hospital and the OPO.

§ 482.102 Condition of participation: Patient and living donor rights.

In addition to meeting the requirements at § 482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.

(a) *Standard: Informed consent for transplant patients.* Transplant centers must have a written informed transplant patient consent process that informs each patient of:

(1) The evaluation process.

(2) The surgical procedure.

(3) Alternative treatments.

(4) Potential medical or psychosocial risks.

(5) National and transplant center-specific outcomes.

(6) The fact that future health problems related to the transplantation may not be covered by the recipient's insurance, and that the recipient's ability to obtain health, disability, or life insurance may be affected.

(7) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor.

(8) His or her right to refuse transplantation.

(b) *Standard: Informed consent for living donors.* Transplant centers must implement a written living donor informed consent process that informs the prospective living donor of all aspects of and potential outcomes from living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:

(1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.

(2) The evaluation process.

(3) The surgical procedure, including post-operative treatment.

(4) The availability of alternative treatments for the transplant recipient.

(5) The potential medical or psychosocial risks to the donor.

(6) The national and transplant center-specific outcomes for both donors and recipients.

(7) The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected.

(8) The donor's right to opt out of donation at any time during the donation process.

(c) *Standard: Notification to patients.* Transplant centers must notify patients placed on the center's waitlist of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

(1) A transplant center served by a single transplant surgeon or physician must inform patients placed on the center's waitlist of:

(i) The potential unavailability of the transplant surgeon or physician; and

(ii) Whether or not the center has a mechanism to provide an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies.

(2) At least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must:

(i) Inform patients on the center's waitlist of this fact and provide assistance to waitlist patients who choose to transfer to the waitlist of another Medicare-approved transplant center without loss of time accrued on the waitlist; and

(ii) Inform Medicare beneficiaries added to the center's waitlist that Medicare will no longer pay for transplants performed at the center after the effective date of the center's loss of approval.

§ 482.104 Condition of participation: Additional requirements for kidney transplant centers.

(a) *Standard: End stage renal disease (ESRD) services.* Kidney transplant centers must furnish directly transplantation and other medical and surgical specialty services required for the care of ESRD patients.

(b) *Standard: Dialysis services.* Kidney transplant centers must furnish inpatient dialysis services directly or

under arrangement. Such kidney dialysis centers or units must meet the Conditions for Coverage of Suppliers of ESRD Services contained in part 405 subpart U of this chapter.

(c) *Standard: Participation in network activities.* Kidney transplant centers must cooperate with the ESRD Network, designated for its geographic area, in fulfilling the terms of the Network's current statement of work.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

1. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh) unless otherwise noted).

Subpart B—Special Requirements

3. Section 488.61 is added to subpart B to read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

For the purposes of this subpart, the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A apply to transplant centers, including the periodic review of compliance and approval contained in § 488.20.

(a) *Initial approval procedures.* A transplant center can submit a letter of request to CMS for Medicare approval at any time.

(1) The letter, signed by a person authorized to represent the center (for example, a chief executive officer), must include:

(i) The hospital's Medicare provider I.D. number;

(ii) Name(s) of the designated primary transplant surgeon and primary transplant physician; and,

(iii) A statement from the OPTN that the center has complied with all data submission requirements.

(2) To determine compliance with the outcome measure requirements contained at § 482.80(c), CMS or its designee will review the 1-year patient and graft survival data contained in the Scientific Registry of Transplant Recipient's (SRTR's) most recent center-specific reports.

(3) If both of the conditions in § 482.80(b)(4) apply, the center may request the SRTR to prepare a customized report of the center's 1-month patient and graft survival data for the previous 1-year period. CMS or its designee will determine compliance with the outcome measure requirements contained at § 482.80(b) using the data contained in these customized reports.

(4) If CMS or its designee determines that a transplant center has met the data submission and outcome measure requirements of § 482.80, CMS or its designee will conduct a survey and review the center's compliance with the conditions of participation contained at § 482.68 through § 482.76 and § 482.90 through § 482.104 using the procedures described at 42 CFR part 488, subpart A.

(5) If a transplant center seeking Medicare approval is found to be in compliance with all the conditions of participation contained at § 482.68 through § 482.104, except for § 482.82 (Re-approval Requirements), CMS will notify the transplant center in writing of the effective date of its Medicare-approval.

(6) CMS or its designee will notify the transplant center in writing if it is not Medicare approved.

(7) Initial approval of a transplant center will be for 3 years.

(b) *Re-approval procedures.* Once Medicare-approved, a transplant center must be in compliance with all the conditions of participation for transplant centers contained at § 482.68 through § 482.104, except for § 482.80 (initial approval requirements) throughout the 3-year approval period.

(1) At least 180 days before the end of the 3-year approval period, CMS, or its designee, will review the transplant center's data in making re-approval determinations.

(i) To determine compliance with the data submission requirements contained at § 482.82(a), CMS or its designee will request data submission data from the OPTN for the previous 3 calendar years.

(ii) To determine compliance with the outcome measure requirements at § 482.82(c), CMS or its designee will review the data contained in the most recent SRTR center-specific reports.

(2) If CMS or its designee determines that a transplant center has met the data submission and outcome measure requirements contained at § 482.82, the transplant center will be re-approved for 3 years.

(3) If CMS or its designee determines that a transplant center has failed to meet the data submission or outcome measure requirements contained at § 482.82, the transplant center will be surveyed for compliance with § 482.68 through § 482.76 and § 482.90 through § 482.104 using the procedures described at 42 CFR part 488, subpart A.

(4) CMS or its designee will notify the transplant center in writing if it is re-approved or if its approval is being revoked. If re-approved, CMS or its designee will notify the transplant center of the effective date of the re-approval.

(c) *Loss of Medicare Approval.* Centers that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A center that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in § 488.61(a);

(2) Be in compliance with §§ 482.68 through 482.104, except for § 482.82 (Re-approval Requirements), at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the center as a result of the loss of its Medicare approval status.

(Catalog of Federal Domestic Assistance Program No. 13.773 Medicare—Hospital Insurance Program; and No. 13.774, Medicare-Supplementary Medical Insurance Program)

Approved: July 30, 2004.

Tommy G. Thompson,

Secretary.

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 405, 410, et al.

Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 400, 405, 410, 412, 413, 414, 488, and 494

[CMS–3818–P]

RIN 0938–AG82

Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that end stage renal disease (ESRD) dialysis facilities must meet to be certified under the Medicare program. The revised requirements focus on the patient and the results of the care provided to the patient, establish performance expectations for facilities, encourage patients to participate in their care plan and treatment, eliminate many procedural requirements from the current conditions for coverage, and preserve strong process measures when necessary to promote patient well being and continuous quality improvement. These changes are necessary to reflect the advances in dialysis technology and standard care practices since the requirements were last revised in their entirety in 1976.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 5, 2005.

ADDRESSES: In commenting, please refer to file code CMS–3818–P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments*. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3818–P, PO Box 8012, Baltimore, MD 21244–8012.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Robert Miller (410) 786–6797, Teresa Casey (410) 786–7215, and Rachael Weinstein (410) 786–6775 (Conditions for Coverage and Quality Standards). Jan Tarantino, (410) 786–0905 (Survey and Certification).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3818–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

AKF American Kidney Fund
AAMI Association for the Advancement of Medical Instrumentation
ANNA American Nephrology Nurses Association
AHRQ Agency for Healthcare Research and Quality
AED Automatic external defibrillator
AIA American Institute of Architects
ANSI American National Standards Institute
BBA Balanced Budget Act of 1997
BONENT Board of Nephrology Nursing Examiners Nursing and Technology
BUN Blood urea nitrogen
CAHPS Consumer Assessment of Health Plans Survey
CBC Center for Beneficiary Choices
CDC Centers for Disease Control and Prevention
CHI Consolidated Health Informatics
CEO Chief executive officer
CLIA Clinical Laboratory Improvement Amendments
CMS Centers for Medicare and Medicaid Services
CPG Clinical practice guidelines
CPM Clinical performance measures
CPR Cardiopulmonary resuscitation
CROWN Consolidated Renal Operations in a Web-enabled Network
DHHS Department of Health and Human Services
DME Durable medical equipment
DOQI Disease Outcomes Quality Initiative
DSN Dialysis Surveillance Network
EMS Emergency medical system
ESRD End stage renal disease
FDA Food and Drug Administration
HHA Home health agency
HIPAA Health Insurance Portability and Accountability Act of 1996
ICH In-center hemodialysis
IOM Institute of Medicine
IT Information technology
LSC Life Safety Code
MedPAC Medicare Payment Advisory Commission
MSW Master's degree social worker
NANT National Association of Nephrology Technicians
NF Nursing facility
NFPA National Fire Protection Association
NIH National Institutes of Health
NISTA National Institute of Standards and Technology Act
NKF National Kidney Foundation
NKF-K/DOQI National Kidney Foundation's Kidney Disease Outcomes Quality Initiatives
NNCC Nephrology Nursing Certification Commission
NNCO National Nephrology Certification Organization
NQF National Quality Forum
NTTAA National Technology Transfer and Advancement Act of 1995
OBRA 1990 Omnibus Reconciliation Act 1990
OIG Office of the Inspector General
OMB Office of Management and Budget
QAPI Quality assessment and performance improvement
RPA Renal Physicians Association
RRG Rapid response group
SNF Skilled nursing facility
VISION Vital Information System to Improve Outcomes in Nephrology
URR Urea reduction rate
USRDS United States Renal Data System

I. Introduction and the Provision of Reference Materials

A. Introduction

The Centers for Medicare and Medicaid Services (CMS) is committed to modernizing the existing regulations that are based on largely procedural standards. One of our key initiatives is to revise many of the health and safety conditions to focus on the patient's experience with care in the delivery setting, patient outcomes of care, and the elimination of unnecessary procedural requirements.

In concert with the Administration's regulatory reform initiative, we believe that new ESRD regulations should—

- Be founded on evidence;
- Be patient-centered;
- Promote outcomes desired for Medicaid and Medicare beneficiaries as well as others served by participating ESRD suppliers of services;
- Establish a framework for the collection and reporting of consensus-driven performance standards;

- Set clear expectations for dialysis facility accountability; and
- Stimulate improvements in processes, outcomes of care, and beneficiary satisfaction.

In addition, the new ESRD conditions for coverage must comport with our national performance measurement strategy, which consists of three principles: (1) Performance measures should be consumer and purchaser-driven; (2) performance measures should be in general, commonly-used terms, and their associated collection tools should be generally available at little or no cost to dialysis facilities; and (3) the content and collection of data and performance measures derived from that data should be standardized.

B. Provision of Informational and Review Aids

In our development of the proposed rule, we have included references to a number of reports, articles, and other documents in the preamble. To indicate the source of this information, we have provided a brief parenthetical acknowledgement at the end of referenced statement and have provided a full citation for the reference in the bibliography (*see* section of VIII.C. of this preamble). Other informational and review aids incorporated in this proposed rule include—

- A table of contents;
- A list of acronyms;
- A chart listing the new provisions (*see* section VIII.A. of this preamble); and
- A crosswalk of the existing requirements to the proposed requirements (*see* section VIII.B. of this preamble).

II. Background

A. History

ESRD is a kidney impairment that is irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life. Dialysis is the process of cleaning the blood artificially with special equipment when the kidneys have failed.

Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603) originally extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. The ESRD program became effective July 1, 1973, and initially operated under interim regulations published in the **Federal Register** on June 29, 1973 (38 FR 17210). In the July 1, 1975 **Federal Register** (40 FR 27782), we published a proposed rule that revised sections of the regulations relating to:

- The Medicare conditions for coverage for suppliers of ESRD services;
- Certification procedures;
- Establishment of minimal utilization rates;
- Designation of ESRD network areas;
- Establishment of Network Coordination Councils; and
- The provision of a Medical Review Board.

A comment period lasting 60 days followed and comments were carefully considered. On June 3, 1976 the final rule was published in the **Federal Register** (41 FR 22501). Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292), amended title XVIII of the Social Security Act (the Act) by adding section 1881. Sections 1881(b)(1) and 1881(f)(7) of the Act further authorize the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare reimbursement. In addition, section 1881(c) of the Act establishes ESRD network areas and network organizations to assure that dialysis patients are provided appropriate care.

B. Existing ESRD Regulations

The requirements from section 1881(b), (c), and (f)(7) are implemented in regulations at 42 CFR 405, subpart U, Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services.

The existing regulations describe the health and safety requirements that dialysis facilities and renal transplantation centers must meet to furnish care to Medicare beneficiaries. The regulations in subpart U also include the provision that dialysis facilities be organized into Network areas and describe the role that Networks play in the ESRD program.

The purpose of the existing conditions for coverage (also known as conditions) is to protect dialysis patients' health and safety and to ensure that quality care is furnished to all patients in Medicare-approved dialysis and kidney transplantation facilities. To determine if a facility meets these conditions, the State survey agency performs on-site surveys of the facility. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, we then certify the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis and kidney transplantation is limited to facilities meeting these conditions.

Our decision to propose major changes to the existing conditions is based on several considerations. As discussed above, revising the ESRD requirements is part of our effort to modernize regulations and move toward a patient outcome-based system that focuses on quality assessment and performance improvement. We believe that revising the conditions for coverage will encourage improvement in outcomes of care for beneficiaries. Secondly, the existing ESRD conditions were originally adopted in 1976 and although some amendments have been made they have not been comprehensively revised since that time. The existing requirements for dialysis facilities emphasize the policies and procedures that must be in place to support good patient care, and they focus on a facility's capacity to furnish quality care, rather than on the actual provision of quality care to patients and the outcomes of that care. Third, we wish to incorporate the most recent medical and scientific guidelines and recommendations for dialysis facilities from the Centers for Disease Control and Prevention (CDC), the Association for the Advancement of Medical Instrumentation (AAMI), and recognize current practice guidelines and standards of practice such as the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) clinical practice guidelines (CPGs).

The existing ESRD conditions do not require the facility to operate a patient-centered, outcome-oriented quality assessment and performance improvement program. Moreover, changes have taken place in the delivery of services to dialysis patients, and these advances are not reflected in the existing requirements. Thus, we have concluded that significant revisions to the conditions for coverage for ESRD facilities are essential. The proposed changes reflect improvements in standard care practices, the use of more advanced technology and equipment, and, most notably, a framework to incorporate performance measures viewed by the scientific and medical community to be related to the quality of care provided to dialysis patients.

C. Overview

Since 1994, we have received comments from the renal community at large and we have used the contributions provided by the community in developing the revised conditions contained in this proposed rule. Several renal organizations have offered recommendations regarding the conditions for coverage during the bimonthly public 2001 and 2002 CMS meetings on ESRD topics. Notices of

these were announced on the CMS Web site *(http://www.cms.hhs.gov/opendoor/schedule.asp)*. We believe that many in the community support the overall shift in the proposed conditions from an emphasis on process-oriented requirements to a more patient-centered, outcome-oriented approach. Further, we believe that virtually all members of the community support a quality assessment and performance improvement requirement and the development of a comprehensive data set that will contain information on the characteristics of ESRD facilities, its patient population, as well as outcome measures of patient care.

The fundamental principles that guided us during this collaborative effort to develop new conditions were as follows:

- Ensure that patients' rights and physical safety are protected.
- Stress continuous quality assessment and performance improvement, incorporating, to the greatest extent possible, outcome-oriented, data-driven measures. Thus, the new conditions would invest a major expectation for performance in a requirement that each facility participate in its own quality assessment and performance improvement program. This allows the facility flexibility to create its own self-tailored program of continuous quality improvement. Facilities could be flexible and creative in their approach to patient care and delivery of services as they use their own information to assess and improve patient services, outcomes, and satisfaction.
- Facilitate flexibility in how dialysis facilities meet our performance requirements;
- Eliminate unnecessary administrative policies. Process-oriented standards are only included where we believe they are essential to protect patient health and safety;
- Focus on the continuous, interdisciplinary, integrated care system that a dialysis patient experiences, centered around patient assessment, care planning, service delivery, and quality assessment and performance improvement; and
- Stress patient satisfaction and ongoing patient involvement in the development of the care plan and treatment.
- Finally, in order for the ESRD facility conditions to move from a process and structure orientation toward a more patient-centered, outcome-oriented approach, individual patient and facility specific outcome measures must be identified and evaluated or in the absence of existing measures, they must be developed and validated with community input to ensure they are clinically meaningful and reflect current scientific knowledge.

D. The Establishment of Central Requirements

We are proposing new conditions for coverage for ESRD facilities that revise or eliminate many of the existing requirements and establish critical central requirements. The central requirements of the proposed rule are grouped into three broad categories: (1) Patient safety; (2) patient care (which includes quality assessment and performance improvement); and (3) administration. Subpart A contains general provisions, for example, statutory authority, definitions, and requirements for compliance with Federal, State and local laws and regulations. Subparts B (patient safety) and C (patient care) of the proposed conditions for coverage would focus the facility's efforts on the actual care delivered to the patients, the performance of the dialysis facility, and the impact of the treatment furnished by the dialysis facility on the health status of its patients.

In Subpart B (patient safety), we are proposing to retain and strengthen some process-oriented patient safety provisions that we believe remain highly predictive of ensuring desired outcomes and preventing harmful outcomes. Accordingly, the patient safety requirements incorporate current CDC infection control procedures, retain and update our incorporation by reference of the AAMI standards and guidelines for water quality and dialyzer reuse practices, and incorporate by reference applicable current Life Safety Code (LSC) provisions.

Subpart C (patient care) includes: (1) Requirements that emphasize a dialysis facility's fundamental responsibility to respect and promote the rights of each patient (patient rights); (2) the critical nature of a comprehensive assessment in determining appropriate treatments and achieving desired health outcomes (patient assessment); (3) the interdisciplinary team approach of providing dialysis services to patients and the process by which the interdisciplinary team will achieve effective patient health outcomes (patient plan of care); (4) the quality assessment and performance improvement program which would charge each dialysis facility with the responsibility for carrying out a performance improvement program of its own design to affect continuing improvement in quality outcomes and patient satisfaction; and (5) the consolidation of the various aspects of home dialysis care into a single condition (care at home).

Subpart D (administration) covers the operation of the dialysis facility in a patient outcome-oriented environment, including: (1) Minimum personnel qualifications; (2) the role of the medical director; (3) the facility's relationship with its servicing ESRD network; (4) medical recordkeeping; and (5) minimum operating responsibilities of the facility, including data collection and reporting requirements (governance).

We recognize that there are some who believe that regulations—particularly those that directly affect the health and safety of patients—should be very prescriptive in their detail to ensure that providers do not engage in practices that threaten patient health and safety. Therefore, we invite public comment on this fundamental shift in our regulatory approach, especially in terms of: (1) How we could improve on this approach; (2) what additional requirements could be removed or added to provide greater flexibility; and (3) which existing and new requirements are critical to patient care and safety.

E. Development of Outcome-Based Performance Quality Measures

Sections 1881(b)(5)(B) through (D) of the Act provide authority for us to obtain the data we need from ESRD suppliers. In accordance with these goals, we envision an information system that protects patients' privacy in compliance with the new privacy protections afforded by the Department's health information privacy regulations at 45 CFR Parts 160 and 164. These regulations were developed under the authority of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The data could be accessed by us as well as dialysis patients, the public, dialysis facilities, State survey agencies, ESRD networks, researchers, policy makers, renal physicians, and other professionals providing care to dialysis patients (where permitted by the privacy regulations). This system would provide information to meet the needs of the entire renal community, particularly the patients, to make better choices about care, and to help dialysis providers identify opportunities for continuous improvement in patient care processes.

This proposal is in keeping with our strategic plan to help patients and the public become better informed about the health care services they need and receive so they can make better health

care choices and participate more fully in their care. The availability of information will permit patients to become more active and effective participants in their own care and in their facility's quality improvement process.

1. Dialysis Facility Compare

One of the first steps to make information more available to the public is the CMS Dialysis Facility Compare website at: *http://www.Medicare.gov/Dialysis/Home.asp.* Dialysis Facility Compare contains various dialysis facility characteristics and specific quality measures including the percentage of in-center hemodialysis patients with a urea reduction rate (URR) (a measure of the adequacy of dialysis) equal to or greater than 65, the percentage of patients treated with Epogen who have hematocrits of 33 percent or greater (reflecting adequately managed anemia), and patient data categories on every dialysis facility approved to participate in the Medicare program.

2. Dialysis Facility Data Reporting Requirements

Sections 1881(b)(5)(B) through (D) of the Act require ESRD suppliers to furnish all necessary information to CMS, the ESRD networks, and State survey agencies. Moreover, existing regulations at § 405.2133 require that each ESRD facility furnish data and information in a manner and frequency specified by the Secretary. This proposed regulation would continue to require facilities to provide data and other information, but in electronic format, including clinical performance measures (CPM) data, necessary for the administration of the ESRD program.

3. Facility Specific Reports

In 1996, CMS first distributed facility-specific reports to Networks and facilities. These reports were compiled by the University of Michigan, using data from the CMS forms used for patient eligibility and patient death purposes; the CMS claims forms; the certification forms; and facility-specific data on infection control practices collected by the CDC.

The initial reports presented comparative data on patient characteristics, patient outcomes, and facility practice patterns. A common CMS database and common data formulations were used to create these reports. Each year since 1996, these reports have been distributed to ESRD Networks and ESRD facilities. The reports have formed a basis for implementing and understanding quality improvement activities. The data that form the basis for these facility-specific reports are used to report patient outcomes and to develop additional reports.

CMS has expanded the Facility Specific Reports to include a broader array of information, including facility-specific reports for the use of State survey agencies, state-specific reports, and region-specific reports. The facility-specific reports have been improved by the expansion of facility practice pattern information, explanatory text with each report, table and graph modifications, and the inclusion of additional risk-adjusters in the calculations of the standardized mortality ratio.

4. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF–K/DOQI) Clinical Practice Guidelines

In March 1995, the National Kidney Foundation (NKF) initiated the National Kidney Foundation-Dialysis Outcomes Quality Initiative (NKF–DOQI), the first comprehensive effort in nephrology designed to provide evidence-based guidance to clinical care in nephrology. Development of the NKF–DOQI clinical practice guidelines involved a 2-year effort in which independent interdisciplinary workgroups reviewed the available body of scientific literature on hemodialysis and peritoneal dialysis adequacy, vascular access, and anemia. Each workgroup was composed of renal experts from diverse clinical disciplines and renal patients. The workgroups were tasked with developing and promulgating clinical practice guidelines for the treatments of patients with ESRD. Four principles guided the project's decision-making: (1) Use of a high level of scientific and methodological rigor in the guideline development process; (2) commitment to an interdisciplinary approach; (3) independence of the workgroups; and (4) openness of the guideline development process. To that end, the workgroups developed draft guidelines with supporting rationales that included the evidentiary basis for the recommendations.

Draft guidelines were subject to an unprecedented three-stage review process: (1) An advisory council, comprised of 25 experts, provided comments on the initial draft of the guidelines; (2) a variety of organizations (that is, ESRD networks, professional and patient associations, dialysis providers, government agencies, product manufacturers, and managed care groups) were invited by NKF to review and comment on a revised draft of the guidelines; and (3) a final draft of the guidelines was made available for public review by all interested individuals or parties.

Four sets of DOQI clinical practice guidelines were published by the NKF in 1997, including recommended practices for management of anemia, adequacy of hemodialysis, adequacy of peritoneal dialysis, and vascular access. In 2000, the scope of DOQI expanded to encompass the spectrum of chronic kidney disease prior to the need for dialysis services. To reflect this expansion, DOQI became K/DOQI. A total of 114 chronic kidney disease clinical practice guidelines were developed by the workgroups and reviewed by numerous professionals and patients. The NKF has published Bone Metabolism and Disease in Chronic Kidney Disease clinical practice guidelines and Hypertension and Antihypertensive Agents in Chronic Kidney Disease as well as Managing Dyslipidemias guidelines. The latest set of clinical practice guidelines being developed under the K/DOQI umbrella are the CPGs for Cardiovascular Disease in Dialysis patients.

5. CMS ESRD Clinical Performance Measures Project

In 1999, we merged our ongoing ESRD Core Indicators Project, a quality improvement project, originally started in 1994, into a new ESRD Clinical Performance Measures Project (ESRD CPM Project). The ESRD CPM Project is an ongoing effort between us, the ESRD networks, and dialysis facilities to collect performance measures on a representative sample of dialysis patients in the areas of adequacy of dialysis, anemia management, nutrition (that is, serum albumin), and more recently, vascular access (DHHS/CMS/CBC, pp. 1–104). The ESRD CPM Project was developed to implement section 4558(b) of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33). This provision required the Secretary to develop and implement a method to measure and report on the quality of renal dialysis services provided under Medicare no later than January 1, 2000.

The goal of the CPM Project was to identify NKF DOQI guidelines that were suitable for the agency's quality improvement initiatives and to meet the BBA requirement. The ultimate purpose of the project is to assist suppliers of ESRD services in improving the care provided to ESRD patients.

In 1998, we contracted with PRO-West (now named Qualis Health), a Seattle-based private nonprofit healthcare quality improvement organization, to facilitate the process of developing dialysis clinical

performance measures (CPMs) based on the NKF's DOQI (now K/DOQI) guidelines.

The process included several components. The first was to develop a mechanism to assure appropriate participation from the community in order to facilitate the acceptability and utility of the CPMs. The second was to prioritize the NKF DOQI guidelines based on the strength of the evidence supporting the guidelines, the feasibility of developing performance measures, and the significance of the areas addressed to the quality of care delivered to dialysis patients. The third was to identify a limited set of CPMs that could be used to support quality improvement activities as well as assist us in assessing nationally the quality of care delivered to Medicare beneficiaries. The fourth was to develop sampling and data specifications for the CPMs to facilitate measurement. Finally, we requested the development of data collection and analysis strategies to be used to augment the existing national performance measurement system.

The CPM Project was conducted in collaboration with a broad range of stakeholders in the community. In order to facilitate this involvement, participation was solicited through contacts with professional and voluntary associations, presentations at national meetings, and invitations to individuals identified through a variety of sources.

Four expert groups were convened to address each of the topic areas covered by the NKF DOQI guidelines: (1) Hemodialysis adequacy; (2) peritoneal dialysis adequacy; (3) vascular access; and (4) anemia management. The NKF DOQI guidelines were ranked via a survey of renal experts for their suitability as candidates for development of CPMs. All 114 NKF DOQI guidelines were included on a survey tool developed by CMS that was distributed to the rapid response group (RRG) and other expert consultants. Suitability of guidelines was based on clinical importance, feasibility of measurement, and the respondent's assessment of the strength of the evidence supporting the guideline.

We accepted 36 proposed guidelines for further evaluation and the 4 expert groups developed specific review criteria, algorithms, and CPMs selected through the prioritization process described above. The CPM development process was a modification of a methodology described by the Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research (AHCPR)). Candidate guidelines that did not have a strong evidence basis were eliminated from further consideration. Sixteen CPMs were developed based on 22 of 36 candidate NKF DOQI clinical practice guidelines.

Data collection instruments were subsequently developed and submitted to us for field testing. Three data collection tools were developed and pilot tested. The first instrument was intended to collect data for the hemodialysis adequacy, anemia management, and vascular access CPMs from hemodialysis patient records. The second instrument was designed to collect adequacy and anemia management data for peritoneal dialysis patients. The third instrument focused on information about facility policies, procedures, and practices related to selected hemodialysis adequacy CPMs. In the summer of 1999, after field-testing, the CPMs were applied to a sample of 8,853 randomly selected adult hemodialysis patients and 1,650 randomly selected adult peritoneal dialysis patients.

In summary, the NKF DOQI process resulted in a broad set of guidelines amenable to prioritization based on strength of evidence, clinical importance and feasibility. The current NKF K/DOQI guidelines are widely accepted among the renal community and increase the likelihood that future CPMs can be developed and supported by a broad cross-section of stakeholders, including clinical practitioners, industry representatives, professional associations, and others interested in assessment and improvement of the care provided to dialysis patients.

We have been working closely with the ESRD networks and information technology contractors to develop the Vital Information System to Improve Outcomes in Nephrology (VISION) database. VISION is a patient-specific, facility-based, outcome-oriented information system that will enable dialysis facilities to electronically collect and report both demographic and clinical data that can be profiled to assist efforts to improve outcomes of care. VISION will capture, among other things, data from the CMS ESRD CPM Project. VISION will be designed so that Consolidated Health Informatics (CHI) standards will be met.

The CHI establishes health messaging and vocabulary standards that enable data sharing across all Federal systems. Implementation of the CHI standards is prospective (that is, applicable to new systems and systems undergoing major upgrades). Current plans are to upgrade the ESRD Information System within the next 2 to 3 years. Since the CHI standards are prospectively applied, the CHI standards will be incorporated when we upgrade the ESRD information system.

Following the upgrade to the ESRD information system, ESRD facilities will be required to submit data using the new information technology (IT) system. They can accomplish submission of data that is consistent with the CHI standards by either modifying their internal systems or by using mapping tools that are provided by the National Library of Medicine (NLM) at no cost. The CHI standards are posted on the *egov.gov* Web site located at *http://www.whitehouse.gov/omb/egov/gtob/health_informatics.htm.*

6. CPM Data Reporting

ESRD CPM Project data have been collected for 1999, 2000, 2001, and 2002 and published in annual reports. The 2001 ESRD CPM report can be found on the Internet at *http://www.cms.gov/esrd/l.asp.* The data for each year include a random sample, stratified by ESRD network, of adult in-center hemodialysis patients and a random peritoneal dialysis patient sample of 5 percent of adult peritoneal dialysis patients in the nation. The sample size of adult in-center hemodialysis patients was selected to allow us to be 95 percent confident that Network-specific estimates for selected clinical measures are accurate within plus or minus 5 percent. The sample also included a 30 percent ''over sample'' for in-center hemodialysis patients and a 10 percent ''over sample'' for peritoneal dialysis patients to compensate for anticipated nonresponse rates. In 2002, the in-center hemodialysis sample included 8,863 patients and the peritoneal dialysis sample included 1,451 patients. Also, a 5 percent national sample of hemodialysis facilities was drawn, consisting over 200 hemodialysis facilities.

Three data collection tools were used, an in-center hemodialysis form (Form CMS–820), a peritoneal dialysis form (Form CMS–821), and a hemodialysis facility-specific form.

We believe that the ESRD CPM Project is an effective tool to facilitate ESRD quality improvement, and this project has successfully tracked positive improvements in patient outcomes of care in several areas. The 2001 Annual Report for the ESRD CPM Project contains additional Outcomes Comparison Tools (for hemodialysis and peritoneal dialysis). Outcomes Comparison Tools are practical quality improvement instruments that can be used by ESRD facilities to benchmark their performance outcomes against rates at the ESRD network's level

(hemodialysis only) and the nation. Therefore, we are proposing in the Governance condition for coverage (§ 494.180(h)), that all ESRD facilities collect and provide us with ESRD CPM Project data electronically. This proposal applies only to the current CPMs and is discussed in more detail later in this preamble. We will carefully evaluate any revisions to the CPMs as well as any future CPMs, developed in accordance with the National Technology Transfer and Advancement Act of 1995 process (described in the next section of this preamble) for possible inclusion as electronic reporting requirements. The Secretary will provide notice and an opportunity for comment in the **Federal Register** before the CPMs are updated or new measures are adopted.

7. Updating Existing ESRD Patient-Specific Performance Measures and Developing Future ESRD Facility Performance Standards

We would like to propose ESRD performance standards that dialysis facilities would be required to meet as well as propose a method to recognize updates in existing consensus-based patient-specific performance measures. We are proposing to adopt a framework that will utilize existing Federal legislation and operational guidelines. The National Technology Transfer and Advancement Act of 1995 ((NTTAA) Pub. L. 104–113) and OMB Circular A–119 specify circumstances in which Federal agencies should use technical standards developed by voluntary consensus bodies. The phrase ''technical standards'' is defined in the NTTAA at section 12(d)(4) as ''performance-based or design-specific technical specifications and related management systems practices.''

The NTTAA has been implemented by, among other things, the provisions of the Office of Management and Budget (OMB) Circular No. A–119 (63 FR 8546, February 19, 1998). OMB Circular No. A–119 was published to: (1) Revise and clarify policies on Federal use and development of voluntary consensus standards; (2) set policy for conformity assessment activities; and (3) improve the clarity and effectiveness of the previously published (October 20, 1993) circular. By implementing the policies in this circular, we intend to reduce to a minimum our reliance on government-specific standards.

Definitions of terms and phrases within the circular are designed for very broad application, but are meant to be applicable to any specific and appropriate subject matter, including health care performance measures.

The circular defines a ''performance standard'' as a standard that states requirements in terms of required results with criteria for verifying compliance but without stating the methods for achieving required results. ''Voluntary consensus standards'' are defined as standards developed or adopted by voluntary consensus standards bodies, both domestic and international. ''Voluntary consensus standards bodies'' are organizations that plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. One example of a voluntary consensus standards body is the National Forum for Health Care Quality Measurement and Reporting, also known as the National Quality Forum (NQF), which is currently engaged in various projects such as standardizing measures of hospital quality and developing diabetes mellitus treatment performance measures.

The expected products of a voluntary consensus body would include the measures or indicators and standards, as well as explanatory text and other supporting documentation, such as guidelines for reporting the indicators. A voluntary consensus body would make a draft product available for general public review during the development of the measures. When the performance standards are complete, we would evaluate them and then promulgate the standards following the requirements of the Administrative Procedures Act.

We are not advocating the NQF as the voluntary consensus body that is most appropriate to develop ESRD performance standards. We have only provided an illustration of the manner in which performance standards are being developed. Other organizations, for example, the NKF–K/DOQI, also function in a manner consistent with voluntary consensus bodies. Once ESRD facility performance measures are developed by a voluntary consensus body, the Secretary would evaluate those facility performance measures and adopt those that meet our needs for the effective administration of the ESRD program after notice and comment rulemaking required by the Administrative Procedures Act.

We will also reference the NTTAA later in this preamble under our discussion of the Governance condition for coverage (*see* § 494.180(h)).

F. Summary of the Contents of the Proposed Rule

We are proposing to revise both the content and the organization of the existing regulations. The ESRD Network conditions for coverage will remain in part 405, subpart U. Through a separate proposed rule regarding conditions of participation for transplant hospitals, we are proposing to move the renal transplant center conditions to part 482. The ESRD conditions for coverage (health and safety provisions for dialysis facilities) would be moved from existing 42 CFR part 405, subpart U, to a new 42 CFR part 494, where they would follow regulations establishing standards for other Medicare providers, such as the conditions of participation for hospitals (42 CFR part 482), long-term care facilities (42 CFR part 483), and home health agencies (42 CFR part 484). The termination of Medicare coverage and alternative sanctions conditions at § 405.2180 through § 405.2184 will be recodified to § 488.604 through § 488.610. Since many of the existing ESRD conditions would be revised, consolidated with other conditions, or deleted, we also propose to completely renumber and reorganize the requirements. The format for the dialysis facility conditions for coverage represents a dramatic change from the organization of the existing regulations, which contain nearly 20 conditions addressing organizational structure, utilization rate requirements, and other process-intensive requirements. The proposed regulations are divided into four subparts: general provisions, patient safety, patient care, and administration.

The proposed organization of Part 494 is as follows:

Subpart A—General Provisions

§ 494.1 Basis and scope.
§ 494.10 Definitions.
§ 494.20 Compliance with Federal, State, and local laws and regulations.

Subpart B—Patient Safety

§ 494.30 Condition: Infection control.
§ 494.40 Condition: Water quality.
§ 494.50 Condition: Reuse of hemodialyzers and other dialysis supplies.
§ 494.60 Condition: Physical environment.

Subpart C—Patient Care

§ 494.70 Condition: Patient rights.
§ 494.80 Condition: Patient assessment.
§ 494.90 Condition: Patient plan of care.
§ 494.100 Condition: Care at home.
§ 494.110 Condition: Quality assessment and performance improvement.
§ 494.120 Condition: Special purpose renal dialysis facilities.
§ 494.130 Condition: Laboratory services.

Subpart D—Administration

§ 494.140 Condition: Personnel qualifications.
§ 494.150 Condition: Responsibilities of the medical director.
§ 494.160 Condition: Relationship with ESRD network.

§ 494.170 Condition: Medical recordkeeping.
§ 494.180 Condition: Governance.

The following provides a detailed discussion of each new requirement and a discussion of the existing ESRD requirements that have been revised or deleted in this proposed rule.

III. Provisions of Proposed Part 494 Subpart A (General Provisions)

A. Basis and Scope (Proposed § 494.1)

[If you choose to comment on issues in this section please include the caption ''Basis'' at the beginning of your comment.]

Proposed § 494.1, identifies the statutory authority for the regulations. Proposed § 494.1 also states that provisions of part 494 serve as the basis for survey activities for determining whether a dialysis facility meets the conditions for coverage under the Medicare program. We note that the organizational format of the proposed conditions permits the elimination of almost all of the material in existing § 405.2100, Scope of subpart, which consists largely of a description of the contents of the existing ESRD conditions for coverage.

B. Definitions (Proposed § 494.10)

[If you choose to comment on issues in this section please include the caption ''Definitions'' at the beginning of your comment.]

Under proposed § 494.10, we set forth definitions for terms used in the ESRD conditions. Existing § 405.2102 provides a list of 32 definitions. We are proposing to eliminate the definitions of several terms for which we believe the meaning is self-evident, as well as terms that are not used in the revised conditions. We do not believe it is appropriate to have substantive requirements contained in those definitions. Thus, we would move definitions that contain qualification requirements to the appropriate conditions in the proposed rule. We have proposed to retain the definition of ''furnishes on the premises'' and add it to proposed § 494.180 (Governance). We are proposing a modification of the definition of ''home dialysis'' to recognize the assisting role that a family member/caregiver may play. We have previously received questions about whether the definition of ''home'' includes institutional settings such as nursing facilities (NFs) and skilled nursing facilities (SNFs). Please refer to section V.D. of this preamble in which we discuss the unique needs of the NF/SNF dialysis patient and the overall issue. We are soliciting comment on whether the definition of ''home'' for ''home dialysis'' should also include these institutional settings.

We propose to include the following definitions in § 494.10:

- *Dialysis facility* means an entity that provides (1) outpatient maintenance dialysis services; or (2) home dialysis training and support services; or (3) both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter), or a self-care dialysis unit, which furnishes only self-dialysis services.
- *Discharge* means the termination of patient care services by a dialysis facility.
- *Furnishes directly* means the ESRD facility provides the service through its own staff and employees or through individuals who are under contract with the facility to furnish these services personally for the facility. We note that furnishes directly does not apply to companies providing services under contract or arrangement.
- *Home dialysis* means outpatient dialysis performed at home by an ESRD patient (or caregiver) if the individual performing such dialysis has completed the course of training required in § 494.100(a) of this part.
- *Interdisciplinary team* (as required in § 494.80 (Patient assessment)) means the group of persons responsible for providing patient care to each dialysis patient.
- *Self-dialysis* means dialysis performed with little or no professional assistance by an ESRD patient (or caregiver) if the individual performing such dialysis has completed an appropriate course of training as required in § 494.100(a) (Care at Home).
- *Transfer* means a temporary or permanent move of a patient from one dialysis facility to another that requires the transmission of the patient's medical record information to the facility receiving the patient.

C. Compliance With Federal, State, and Local Laws and Regulations (Proposed § 494.20)

[If you choose to comment on issues in this section please include the caption ''Compliance with Laws and Regulations'' at the beginning of your comment.]

Existing § 405.2135 requires that a dialysis facility be in compliance with applicable Federal laws and that a dialysis facility be licensed or approved as meeting applicable standards by the agency of the State or locality responsible for approval. Section 405.2135 further requires a facility to comply with all relevant laws (for example, laws relating to licensure of staff) and requires conformity with other laws (for example, fire safety, equipment maintenance).

We propose to retain the requirement that dialysis facilities must be in compliance with applicable Federal, State, and local laws and regulations pertaining to fire safety, equipment, and any other relevant health and safety issues. We are also proposing that dialysis facilities must be in compliance with the appropriate Federal, State, and local laws and regulations regarding drug and medical device usage. An example of meeting applicable Federal regulations is that the dialysis facility must use FDA-approved/cleared medical devices and adhere to the devices' labelling instructions. We have added these examples because drugs and medical devices are major components of dialysis facilities and compliance with existing laws and regulations in this area is important in ensuring patient safety.

We may find a facility to be in violation of these conditions for coverage if the facility is found out of compliance with any Federal, State, and local law or regulation pertaining to health and safety requirements.

IV. Provisions of Proposed Part 494 Subpart B (Patient Safety)

A. Infection Control (Proposed § 494.30)

[If you choose to comment on issues in this section please include the caption ''Infection Control'' at the beginning of your comment.]

Patients with ESRD have impaired immunological systems and are more at risk of developing serious infections than similarly situated non-ESRD patients. During hemodialysis therapy, there is a potential for patients to be exposed to a variety of microbial pathogens (including blood-borne pathogens) if proper procedures are not meticulously followed. Likewise, peritoneal dialysis patients are at risk of contamination leading to peritonitis if proper procedures are not followed. This proposed rule stipulates that the dialysis facility must provide and monitor conditions to ensure a sanitary environment that prevents the transmission of infectious agents.

The existing standards relating to infection control are contained in § 405.2140(b)(1) and (c). Section 405.2140(b)(1) requires written procedures for controlling hepatitis and other infections. It further specifies that the procedures include surveillance and reporting of infections, housekeeping, handling of waste and contaminants, and sterilization and disinfection. Section 405.2140(c) requires the facility

to employ appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas.

We believe infection control is vital to the health and safety of dialysis patients and others; and therefore, we propose to establish infection control as a separate condition for coverage (§ 494.30). The proposed infection control requirement states that each dialysis facility must provide and monitor a sanitary environment that prevents and controls the transmission of infectious agents, within and between the unit and any adjacent hospital, or other public areas. The proposed requirement sets forth the basic guidelines or procedures that facilities must follow to prevent and control infections.

Proposed § 494.30(a)(1) requires that the facility demonstrate that it follows standard infection control precautions, including the ''Recommended Infection Control Practices for Hemodialysis Units At a Glance'' with the exception of screening for Hepatitis C as explained below. The ''At a Glance'' section is in the publication, ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' developed by the Centers for Disease Control and Prevention (CDC) (DHHS/CDC, 20–21). We propose to incorporate these guidelines to prevent and control cross contamination and the spread of infectious agents. These CDC infection control recommendations specific to the hemodialysis setting were developed in consultation with other Federal agencies and specialists and are based on available knowledge regarding transmission of infectious agents.

Recommended Infection Control Practices for Hemodialysis Units at a Glance

Infection Control Precautions for All Patients

• Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station; remove gloves and wash hands between each patient or station.

• Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before taken to a common clean area or used on another patient.

—Nondisposable items that cannot be cleaned and disinfected (*e.g.*, adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.

—Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.

• When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.

• Do not use common medication carts to deliver medications to patients. Do not carry medication vials, syringes, alcohol swabs or supplies in pockets. If trays are used to deliver medications to individual patients, they must be cleaned between patients.

• Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.

• Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines pressure monitors. Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.

• Clean and disinfect the dialysis station (chairs, beds, tables, machines, etc.) between patients.

—Give special attention to cleaning control panels on the dialysis machines and other surfaces that are frequently touched and potentially contaminated with patients' blood.

—Discard all fluid and clean and disinfect all surfaces and containers associated with the prime waste (including buckets attached to the machines).

• For dialyzers and blood tubing that will be reprocessed, cap dialyzer ports and clamp tubing. Place all used dialyzers and tubing in leak-proof containers for transport from station to reprocessing or disposal area.

SCHEDULE FOR ROUTINE TESTING FOR HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) INFECTIONS

Patient status	On admission	Monthly	Semi-annual	Annual
All patients	HBsAg*, Anti-HBc (total)* Anti-HBs*, Anti-HCV, ALT†			
HBV susceptible, including non-responders to vaccine		HBsAg		
Anti-HBs positive(>10 mIU/mL), anti-HBc negative				Anti-HBs
Anti-HBs and anti-HBc positive		No additional HBV testing needed		
Anti-HCV negative		ALT	Anti-HCV	

Hepatitis B Vaccination

• Vaccinate all susceptible patients against hepatitis B.

• Test for anti-HBs 1–2 months after last dose.

—If anti-HBs is <10 mIU/mL, consider patient susceptible, revaccinate with an additional three doses, and retest for anti-HBs.

—If anti-HBs is >10 mIU/mL, consider immune, and retest annually.

—Give booster dose of vaccine if anti-HBs declines to <10 mIU/mL and continue to retest annually.

Management of HBsAg-Positive Patients

• Follow infection control practices for hemodialysis units for all patients.

• Dialyze HBsAg-positive patients in a separate room using separate machines, equipment, instruments, and supplies.

• Staff members caring for HBsAg-positive patients should not care for HBV susceptible patients at the same time (*e.g.*, during the same shift or during patient change-over).

We are proposing an exception to the CDC recommendation for monthly and semiannual screening for all hemodialysis patients for hepatitis C. Patients with clinical indicators or risk factors for hepatitis C should receive diagnostic testing as deemed necessary by the attending physician. Medicare covers diagnostic testing for hepatitis C on a case-by-case basis, but does not cover blanket hepatitis C screening at this time. According to the CDC, transmission of hepatitis C can be prevented by strict adherence to infection control precautions recommended for all hemodialysis patients.

The ''At a Glance'' page highlights the crucial CDC recommendations that serve as the minimum acceptable infection control practices. This document reproduced above is currently available on the CDC Web site at *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm*.

There is substantial evidence that the CDC guidelines work in preventing the transmission of bloodborne infections. Recommendations for the control of hepatitis B in hemodialysis centers were first published in 1977 and within 3 years there was a sharp reduction in incidence of hepatitis B infection among both patients and staff members in hemodialysis centers (Alter, pp. 860–865).

The entire CDC RR05 report contains recommendations for infection control precautions in greater detail than the ''At a Glance'' highlights. We considered proposing that the entire CDC RR05 document be incorporated by reference. However, we want to be less prescriptive and burdensome in our requirements while protecting patient safety. Dialysis facilities are encouraged to utilize the more comprehensive document when developing their infection control programs. For example, the CDC infection control precautions for all patients identify procedures for cleaning up a blood spill; and detail information on glove use, protective gear, and handwashing. The CDC has issued additional guidance regarding hand hygiene and environmental infection control in the October 25, 2002 and June 6, 2003 issues of the Morbidity and Mortality Weekly Report that dialysis facilities may want to reference in their infection control policies (DHHS/CDC, pp.1–45 and DHHS/CDC, pp. 1–44, respectively).

Existing § 405.2140(b)(1) requires that written policies and procedures must be in effect for preventing and controlling hepatitis and other infections. There is no current requirement in the conditions for coverage addressing patient isolation. However, many facilities have adopted the 1977 CDC guidelines that recommend use of a separate dialysis area, preferably a separate isolation room, for dialyzing hepatitis B surface antigen positive patients. Newly opened hemodialysis units would be required to have isolation rooms for hepatitis B positive patients as described in the ''At a Glance'' section. For existing units in which a separate room is not possible, there would be required to be a separate area removed from the mainstream of activity that also allows for dedicated staff and dedicated dialysis machines. When the facility determines that a patient is infectious (from admission or at least annual testing) the guidelines state that the facility would be required to isolate the infected patient from susceptible patients to prevent the transmission of the disease. We propose to require at § 494.30(a)(2) that a facility implement and maintain patient isolation procedures that prevent and control the spread of infectious agents and communicable diseases.

We also propose at § 494.30(a)(3) that facilities implement appropriate procedures for the handling, storage, and disposal of waste, and for disinfection. Appropriate waste storage and disposal procedures are important not only for the control of infections within the units, but also for the welfare of the unit staff and the community. Since local policies vary, we do not believe it is appropriate to specify the minimum requirements for waste storage and disposal. Rather, facilities should continue to operate in accordance with applicable local laws and accepted public health procedures. We also propose to require that facilities implement protocols for cleaning and disinfection because we believe that adequate disinfection of surfaces, medical devices, and equipment is an important part of a facility's efforts to control and prevent cross-contamination. We propose to add a requirement for the implementation and maintenance of procedures regarding cleaning of surfaces and devices potentially contaminated with blood to prevent patients from coming into contact with a blood-borne pathogen. The CDC RR05 recommendations and dialysis equipment manufacturers' instructions provide valuable information on procedures a facility may adopt to meet this requirement.

We considered proposing to include the American Institute of Architects (AIA) Guidelines for Design and Construction of Hospitals and Health Care Facilities, which outline building requirements pertinent to dialysis facilities. The AIA standards provide guidance to facilities regarding unit design and parts of the guidance relate to infection control. While we believe it is desirable for new units to follow AIA standards, and many States have adopted these as minimum standards, we recognize it may be overly burdensome to require existing dialysis units to adhere to these standards.

We also considered including in the proposed rule the Healthcare Infection Control Practices Advisory Committee's (HICPAC) guidelines entitled ''Hand Hygiene in Healthcare Settings'' and ''Guideline for Preventing Intravascular Device-Related Infections.'' We are inviting comments on whether we should require new dialysis facilities to adhere to AIA design standards or HICPAC guidelines.

We propose requirements for oversight of facility infection control in § 494.30(b). The facility must implement and monitor biohazard and infection control policies and activities within the dialysis unit. Any infection control policies adopted by the facility are only effective when put into action. We propose that facilities must designate a registered nurse as the infection control or safety officer who maintains current infection control information, and reports to the facility's chief executive officer or administrator and quality improvement committee. The infection control nurse must maintain current infection control information including the most current CDC guidelines for the proper techniques in the use of vials and ampules containing medication. For example, facilities should not pool vials of any medications. An outbreak of serratia liquefacies from contamination of erythropoietin at a hemodialysis center serves as a reminder of the importance of the proper handling of medications in protecting the dialysis patient. (Grohskopf, pp. 1491–1497.)

The infection control or safety officer is also responsible for making recommendations regarding infection control training and improvements. The designation of an infection control officer provides a structure for infection control, encourages the maintenance of up-to-date information, and increases accountability for infection control.

We propose to maintain the essence of the existing requirement for surveillance and reporting of the incidence of

infection (§ 405.2140(b)(1)). The facility must analyze and document the incidence of infections to identify trends and establish baseline information on infection incidence as proposed in § 494.30(c). By conducting a trend analysis of infections, the facility will be able to identify opportunities for improvement to prevent or eliminate the spread of infection or communicable disease between patients. By tracking the number and types of infections, the facility can identify areas that require improvement, indicate areas that have improved, define measures to improve outcomes, review implementation of improvement measures, and determine the success of the improvement measures implemented.

In August 1999, the CDC initiated the CDC Dialysis Surveillance Network (DSN), a voluntary national surveillance system monitoring bloodstream and vascular infections by individual hemodialysis centers. The purposes of the DSN are to provide a method for individual hemodialysis centers to record and track rates of vascular access infections, other bacterial infections, and intravenous antimicrobial starts, and to provide rates for comparisons among various dialysis centers. The infection control or safety officer should look toward the CDC surveillance system as a resource. Information on the DSN may be found on the following Web site: *http://www.cdc.gov/ncidod/hip/Dialysis/dsn.htm*.

The existing standard governing infection control (§ 405.2140(b)(1)) contains a requirement governing reuse of dialyzers which states that when dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation, and storage of reused items conform to the requirements for reuse. This standard is redundant with the reuse requirements included in the AAMI guidelines that are incorporated by reference in both the existing and proposed regulations. Therefore, we are proposing to delete the requirement in § 405.2140(b).

Existing § 405.2140(c) requires that written patient care policies specify the functions of facility personnel and self-dialysis patients with respect to contamination prevention. We are proposing to delete the ''written policy'' requirement because it is process-oriented and a paperwork burden.

As noted above, the existing conditions for coverage require policies for surveillance and reporting of infections at § 405.2140(b)(1). In this proposed rule, reporting requirements for communicable diseases are listed at § 494.30(d). The facility must maintain a current list of the communicable diseases that must be reported according to Federal, State, and local requirements, and have a procedure for reporting these communicable diseases, which allows the facility to accurately report incidences of communicable diseases. These requirements are in concert with the present standard operating practices in dialysis facilities.

B. Water Quality (Proposed § 494.40)

[If you choose to comment on issues in this section please include the caption ''Water Quality'' at the beginning of your comment.]

Water quality is of vital importance to a dialysis facility and to the patient. Because we believe water quality is an essential health and safety issue for ESRD patients, we are proposing a condition for coverage for water quality in this proposed rule.

The hemodialysis patient's blood has the potential to be exposed to toxic contaminants present in water. Some chemical contaminants are not normally harmful when present in small amounts in usual physiological fluids. However, since hemodialysis patients are exposed to the large volume of water that is used to make dialysate, chemical contaminants can be dangerous to them. If water supplies are biologically or chemically contaminated, the patient may experience infection or other adverse consequences. Limits on bacterial growth in water and dialysate are necessary to prevent high bacterial counts associated with pyrogenic reactions (fevers, chills, nausea).

The patient's exposure to contaminated water can be through water mixed with dialysate, water mixed with reprocessing germicides, or water used to flush out dialyzers. Contamination of the water system with organic and inorganic chemicals, bacteria, and endotoxins can result in adverse patient reactions, such as hemolysis, bacteremia, pyrogenic reactions, or death. Exposure to some contaminants such as aluminum can cause chronic health problems, while exposure to other contaminants such as fluoride can be fatal. Therefore, a dialysis facility must monitor the quality of the water used in treatments, as well as monitor the equipment used in water treatment.

In the September 18, 1995 **Federal Register** (60 FR 48039), we published a final rule that incorporated by reference the 1992 AAMI standard for water quality and the AAMI recommended guidelines for monitoring purity of water as published in the ''Hemodialysis Systems,'' ANSI/AAMI RD5: 1992, sections 3.2.1, 3.2.2, and Appendix B, sections B1–B5 (American National Standards Institute 1992). Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally. AAMI standards and guidelines undergo a regular 5-year review process that allows updates and revisions. These consensus recommendations are intended to help ensure patient safety.

The AAMI guidelines referenced in the existing conditions for coverage have been replaced by more recent AAMI guidelines, and therefore, we are proposing to incorporate new AAMI references. The ANSI/AAMI RD5: 1992 document has been replaced by ''Concentrates for Hemodialysis'' ANSI/AAMI RD61: 2000, ''Water Treatment Equipment for Hemodialysis Applications'' ANSI/AAMI RD62: 2001, and ''Dialysate for Hemodialysis'' ANSI/AAMI RD 52:2004. These publications update the information on monitoring of water quality currently incorporated by reference in § 405.2140(a)(5) and provide additional recommended practices.

We are proposing to incorporate by reference the following revised AAMI water quality standards, published in ''Water Treatment Equipment for Hemodialysis Applications,'' 4.2.1 and 5.2.1, Water Bacteriology; 4.2.2 and 5.2.2, Maximum Level of Chemical Contaminants; and 4.3, Water Treatment Equipment requirements (American National Standards Institute, 2001). The updated water purity standards, section 4.2.1, now include bacteria and endotoxin action levels that identify the concentration at which steps (such as system disinfection and retesting) should be taken to reduce the levels to an acceptable range. Facilities must take corrective action when these action levels are met or exceeded.

The AAMI list of contaminants for which water must be tested has been expanded to include antimony, beryllium, and thallium. These chemicals were added based on changes in the United States Environmental Protection Agency Safe Drinking Water Act 1996 (Pub. L. 104–182). AAMI's rationale for testing water for these contaminants may be found in the appendix of the ANSI/AAMI RD62: 2001 document at A.4.2.2 (American National Standards Institute, 2001).

We have also included the updated AAMI requirements for water treatment equipment. This inclusion provides clarity by defining the minimum

standards for water treatment equipment needed to protect patient safety. Proper hemodialysis is dependent on the quality of the dialysate. A water system consisting of the proper components and maintained in accordance with the manufacturers' instructions, can be expected to produce dialysate that meets the AAMI standards and produces acceptable patient outcomes. The minimum safety requirements are specified in the AAMI standards referenced in proposed § 494.40(a)(1)(iii) for each component of the water treatment system (that is, deionization, reverse osmosis, monitors, sediment filters, carbon absorption media, automatically regenerated water softeners, storage tanks, piping systems; and when used, ultrafilters, ultraviolet irradiators, hot water disinfection systems, ozone disinfection systems, and tempering valves). A water treatment system consisting of the proper equipment components as identified by AAMI (and the Food and Drug Administration (FDA)) is standard practice in dialysis facilities.

We are proposing state of the art water purity monitoring guidelines outlined in ANSI/AAMI RD52: 2004 ''Dialysate for Hemodialyzers'' section 7.2.1 document. Proposed § 494.40(a)(2) incorporates by reference the section that specifies the frequency of water purity testing to insure meeting the AAMI limits specified in § 494.40(a)(1)(i) and (ii) as follows:

- Bacteria and bacterial endotoxin levels of water must be measured—

++ In established systems at least monthly;

++ In newly-installed systems at least weekly until an established pattern of compliance can be demonstrated.

- At least monthly in samples drawn from—

++ The first and last outlets of the water distribution loop;

++ Where water enters the dialyzer reprocessing equipment;

++ Outlet of the water storage tanks, if used;

++ Concentrate or from the bicarbonate concentrate mixing tank.

- Bacteria levels must be measured at least monthly from a sample of two or more dialysis machines, this sampling must ensure that all machines are tested at least once a year.

- Chemical analysis of water purity must be done at least once a year and when—

++ The system is installed;

++ Membranes are replaced if using a reverse osmosis system;

++ Seasonal variations in source water suggest worsening water quality; and

++ Reverse osmosis rejection rates, which are monitored daily using continuous-reading monitors that measure product water conductivity, fall below 90 percent.

Ultrapure dialysate has received attention in the clinical literature and the working draft AAMI standards ''Dialysate for Hemodialysis'' RD52 contains guidelines pertaining to ultrapure dialysate. We are not proposing a requirement for ultrapure dialysate at this time but we do invite comment on this topic. We also welcome comment on the requirements for the frequency of water purity testing.

In addition, we are proposing further evidence-based requirements consistent with AAMI guidelines within the proposed water quality condition. The existing conditions for coverage do not address requirements for the water treatment equipment, although the interpretive guidelines for § 405.2140(a)(5)(ii) do advise that water treatment systems must include a carbon tank and either a reverse osmosis or deionization system (DHHS/CMS, 1995). We are proposing that the water treatment system must include a reverse osmosis or deionization component that conforms to the referenced water treatment equipment for hemodialysis applications AAMI guidelines 4.3.5 and 4.3.6. This is in keeping with current standards of practice, which are widely adhered to by dialysis facilities. The reverse osmosis process serves to remove dissolved salts, bacteria, viruses, pyrogens, and organic molecules. Deionization serves to remove ions. A reverse osmosis system along with pretreatment is used in the vast majority of all dialysis centers and this requirement should not present an additional burden to hemodialysis centers.

A consequence of patient exposure to high levels of chloramine via dialysis is hemolytic anemia, which may be life-threatening. The 1992 AAMI guidelines specified at least once daily testing of purified water for chlorine/chloramine levels. It is now widely recognized that testing before each shift of hemodialysis sessions, which is the current standard in many dialysis units, provides greater patient safety. Therefore, we are proposing at § 494.40(c)(2) to require chlorine/chloramine testing of water samples that must be taken from the exit port of the initial chlorine/chloramine removal component (or carbon tank) prior to each patient shift or every 4 hours, whichever is shorter, during operation of the water system, unless the facility ensures on a daily basis that the source water is chlorine/chloramine free by way of testing. In addition, proposed § 494.40(c)(2)(i) would require subsequent testing from the backup component (or second carbon tank) if the test shows greater than 0.50 parts per million (ppm) for free chlorine or 0.10 ppm for chloramine. Due to the dangers of chlorine/chloramine exposure, each water purification system must provide for the adequate removal of chlorine/chloramine and this is standard operating practice in hemodialysis facilities. In conformity with the referenced AAMI guidelines at 4.3.9, carbon tanks used for the removal of chlorine/chloramine must contain granulated activated carbon and provide adequate empty bed contact time to be effective. A backup component or second carbon tank must be in place for failure of the first line component for chlorine/chloramine removal (or first carbon tank), in order to protect patients during a hemodialysis session.

Dialysis facilities would be required to follow the applicable FDA recommendations in ''Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis'' that 2 carbon tanks be installed in series with empty bed contact time of 10 minutes (DHHS/FDA, 1997). The second carbon tank provides the backup safety measure. Some dialysis facilities have three or four carbon tanks that provide even more assurance there will not be chloramine breakthrough. We invite comment as to whether our proposed conditions for coverage that include expanded water equipment requirements are still too minimal. In addition, we are requesting comments on whether the current AAMI guidance regarding carbon tanks is adequate to address all potential health and safety problems associated with chlorine, chloramines, and unannounced variations in source water. Specifically, we seek comments regarding where there is sufficient evidence to require Medicare-participating dialysis facilities to maintain at least two carbon tanks (that is, primary and backup) as part of their water treatment system, regardless of the current composition of its source water.

We are proposing in § 494.40(e) to require active surveillance of hemodialysis patient reactions during and following dialysis, particularly when there are adverse reactions that might be associated with a problem with the water purification system. The facility must take steps to protect patient safety and obtain the appropriate blood and dialysate cultures. Evaluation of the water purification system must be undertaken as well as any necessary corrective action (§ 494.40(d)).

If chlorine/chloramine levels in treated water from the last backup component (or carbon tank) are above the AAMI standards as required in proposed § 494.40(a)(1)(ii), dialysis treatments must be immediately stopped to protect patients from exposure to chlorine/chloramine as proposed in § 494.40(c)(2)(ii). The medical director, who is ultimately responsible for water quality, must be notified immediately and corrective action taken. A corrective action plan is also required (see § 494.40(d)) whenever any of the water purity action levels or standards, including but not limited to, chemical, microbial, and endotoxin, are detected.

We propose to add a requirement, consistent with in the AAMI document RD52:2004, that specifies that once mixed, bicarbonate concentrate must be used within the time specified by the manufacturer of the concentrate and may not be mixed with fresh concentrate. The holding of the bicarbonate concentrate presents the risk of bacterial growth and should be avoided.

We considered addressing water quality for home dialysis patients in this condition, but we decided instead to include a requirement that the facility monitor water used by its home dialysis patients to ensure that the water meets the AAMI standards under the proposed ''care at home'' condition for coverage (§ 494.100). Addressing all home dialysis issues under a single condition simplifies the organization of the regulations and eliminates the need for readers to refer to separate sections for the requirements for home dialysis services.

C. Reuse of Hemodialyzers and Bloodlines (Proposed § 494.50)

Section 1881(f)(7) of the Act requires the Secretary to establish protocols for reuse of hemodialyzers for those facilities that voluntarily elect to reuse the filters. The Act further states that dialysis facilities that fail to follow the reuse protocol will be subject to denial of participation in the Medicare program and denial of payment for dialysis treatment not furnished in compliance with the reuse protocol.

In hemodialysis the patient's blood is cleansed of impurities when it passes through the filter (hemodialyzer) of a hemodialysis machine. There are various techniques that allow some of these filters to be reused under certain conditions. Reuse involves cleaning, disinfecting, and preparing such hemodialysis devices for subsequent use for the same patient. Although the potential exists for adverse patient outcomes from reuse, reprocessing and reuse of dialyzers are safe when proper techniques are utilized.

The existing regulation at § 405.2150 requires ESRD facilities reusing hemodialyzers to meet the guidelines and standards adopted by AAMI and issued in July 1993, as ''Reuse of Hemodialyzers'' (American National Standards Institute, 1993). We are proposing to retain this requirement in the proposed rule but to incorporate by reference the newly revised version and associated amendment (ANSI/AAMI RD47: 2002 and ANSI/AAMI RD47: 2002/A1: 2003) which replaces the 1993 version. This document received final AAMI approval on November 7, 2002.

Some in the renal community believe that we should not incorporate the CDC guideline that prohibits reuse for hepatitis B patients. They believe there is no documentation that reuse contributes to the spread of hepatitis or that it negatively affects the patient with hepatitis. In addition, they indicated that this prohibition is costly to facilities because a new dialyzer must be used for each session.

Hepatitis B is a highly contagious and potentially damaging illness, especially for a dialysis patient. Thus, the CDC has for many years recommended extreme caution and isolation for those patients who are Hepatitis B positive. Many physicians, nurses and other professionals involved in the dialysis field have similarly supported the position of extreme caution in treating the hepatitis B positive patient. The 2001 CDC guidelines advise against the reprocessing of dialyzers used for patients who have Hepatitis B because of the risk to facility staff. The hepatitis virus is relatively stable in the environment and has been shown to remain viable for several days on surfaces (via blood spills). While there may be no appreciable evidence to demonstrate that reuse would increase the spread of hepatitis B, there is not conclusive evidence that reuse in this population is safe. At this time we propose to maintain the CDC guidelines prohibiting reuse for hepatitis B patients to minimize the incidence of this mode of transmission.

We are also proposing at § 494.50(b)(2) that the hemodialyzer manufacturer recommendations be followed, or if an alternate method for reprocessing hemodialyzers is used, that the facility have documented evidence that the method is safe and effective. According to FDA guidance, hemodialyzer labeling should reflect the clinical use of a hemodialyzer, and whether it is intended for single or multiple usage (DHHS/FDA, 1995). Only hemodialyzers and bloodlines labeled for multiple use may be reused. In addition, manufacturers of reusable hemodialyzers are required to provide adequate instructions for safe and effective reuse in accordance with 21 CFR 801.5. If the facility chooses to use an alternate method for reprocessing hemodialyzers there must be sufficient scientific evidence that the method is safe and effective. This flexibility is provided to allow for the use of newer and improved technologies that are proven safe in scientific studies which may become available in the future. The FDA approved label recommendations for the proper use of the device must be adhered to by dialysis facilities.

Existing § 405.2150(a)(2) states that to prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. We have received informal suggestions that we alter the current language because many facilities use bleach as part of the reuse process to flush and clean blood deposits before the actual germicide soaking process is initiated. However, for purposes of reuse, we consider bleach to be a cleansing agent, not a germicide. The requirement to discard dialyzers treated with a different germicide does not apply to bleaching. Nonetheless, since the language appears to be confusing to some, we are proposing to clarify the provision in proposed § 494.50(b)(3) by inserting the phrase ''other than bleach.''

Some in the renal community and on the AAMI RD47 workgroup stated that discarding dialyzers exposed to a second germicide was expensive and unnecessary if air pressure leak test results indicated the dialyzer was still effective. However, we are proposing to retain the requirement in existing § 405.2150 that if a dialyzer is exposed to a second germicide it must be discarded because we are concerned that exposure to different germicides may cause membrane leaks. While we recognize that it may be considered wasteful by some to discard dialyzers with test values that indicate they are still effective, we believe this is a necessary safety measure. We do not have sufficient evidence that clearly supports the safety of using multiple germicides on hemodialyzers. We welcome comment on the issue of multiple germicide use in reused hemodialyzers.

Existing § 405.2150(a)(3) requires that facilities take appropriate blood cultures at the time a patient has a febrile response and discontinue reuse of

hemodialyzers in the case of pyrogenic reactions, bacteremia, or unexplained reactions possibly associated with ineffective reprocessing, until the entire reprocessing system is evaluated. We have been advised that a single febrile response in one patient can be the consequence of many different etiologies not related to reuse, including an infected access, a current infection, or contamination of the water purification system. Members of the renal community suggested that a febrile reaction in a single patient is rarely attributed to dialyzer reuse. Facilities do not believe it is necessary to terminate reuse or order blood cultures when a febrile reaction occurs in only a single patient. It was suggested that a facility need only respond through aggressive evaluation of its water purification system, dialysis concentrates, and reuse system when the surveillance of febrile events reveals a cluster of febrile patients. Based on this evaluation, the facility can make an appropriate clinical decision concerning termination of reuse. As a result, we are proposing in § 494.50(c) to revise the regulations to state that a facility need only obtain blood and dialysate cultures and evaluate its reprocessing and water purification systems in response to an adverse reaction when clinically indicated. If the evaluation indicates that the facility should discontinue reuse, we expect facilities to have established contingency plans, suspend the reuse of hemodialyzers until the problem has been corrected, and report the adverse outcomes to the FDA and other agencies as required by Federal, State or local laws and regulations.

Existing § 405.2150(c) lists 4 requirements applicable to a facility that reuses bloodlines. Facilities must: (1) Limit the reuse of bloodlines to the same patient; (2) not reuse bloodlines labeled for ''single use only''; (3) reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the FDA in accordance with the premarket notification (see section 510(k) of the Food, Drug, and Cosmetic Act and 21 CFR 876.5860 of the regulations); and (4) follow the FDA-accepted manufacturer's protocol for reuse of that bloodline. We propose to maintain the first requirement to limit the reuse of bloodlines to the same patient because the risk of transmitting blood-borne pathogens is so high, and reusing for the same patient limits the risk of cross-contamination. We also propose to maintain the third and fourth requirements, that is, a facility may reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the FDA; and that the facility must follow the FDA-accepted manufacturer's protocol for reuse of the bloodline. With these requirements, the facility must follow any specific instructions listed by the FDA, as well as any guidelines by the manufacturer that may not be discussed in the FDA regulations. We are proposing to delete the second existing requirement that facilities not reuse bloodlines labeled for ''single use only'' because it is redundant with the existing third and fourth requirements. Since the FDA would not recommend reuse on bloodlines labeled ''single use only,'' there is no need to maintain the requirement.

D. Physical Environment (Proposed § 494.60)

[If you choose to comment on issues in this section please include the caption ''Physical Environment'' at the beginning of your comment.]

The existing physical environment condition (§ 405.2140) stipulates that the physical environment in which dialysis services are furnished afford a functional, sanitary, safe, and comfortable setting for patients, staff, and the public. The existing regulation consists of four separate standards concerning building and equipment, favorable environment for patients, contamination prevention, and emergency preparedness. We propose to refine the physical environment section to include only those elements that relate directly to the physical surroundings of the dialysis facility and to relocate the remaining elements to other sections in the proposed rule that relate more closely to those subject areas.

The existing building and equipment requirements in § 405.2140(a), include fire safety procedures, equipment maintenance, facility maintenance, and water treatment. Based on the experience and suggestions of our surveyors, we propose to establish separate standards for the building itself in proposed § 494.60(a) and equipment in proposed § 494.60(b). We propose to maintain the existing requirement (described in § 405.2140(a)) that the building in which dialysis services are furnished be constructed and maintained to ensure the safety of patients, the staff, and the public. The dialysis facility should be free from hazards that may bring harm to the patients, the staff, and the public.

The existing language of § 405.2140(a)(2) stipulates that all electrical and other equipment used in the facility be maintained free of defects that could present a potential hazard to patients or personnel and that there is a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility. We propose at § 494.60(b) to maintain the essence of this requirement but to clarify that all equipment is maintained in accordance with the manufacturer's recommendations. Based on their experience with the equipment, we believe manufacturers have the most knowledge about routine maintenance and recommended repair.

Existing § 405.2140(b) requires each facility to maintain a favorable environment for patients; and the facility must be maintained and equipped to provide a functional, sanitary, and comfortable environment with an adequate amount of well-lighted space for the services provided. The existing language in this standard combines several different concepts, including sanitary environment and infection control, and we propose to address each subject in separate sections of the regulation. As a result, we are proposing at § 494.60(c) to include only those standards regarding the safety and comfort of each patient.

Since the proposed conditions are outcome-oriented, we believe that we do not need to specify all the process requirements that a facility must meet to provide a dialysis environment in which the patient can receive quality care. Each facility can develop its own strategies and techniques as long as the space for treating each patient is sufficient to provide needed care and services, prevent cross-contamination, and accommodate medically needed emergency equipment and staff. Existing § 405.2140(b) also requires the facility to provide a well-lit space. We propose to delete this requirement because it is too subjective to be meaningful, and we believe this detail is better left to the judgment of the facility staff.

We expect the dialysis facility to provide patients with a comfortable environment. Existing § 405.2140(b)(4) requires that heating and ventilation systems be capable of maintaining adequate and comfortable temperatures. We recognize that not all patients are comfortable at the same temperature; and therefore, proposed § 494.60(c)(2) specifies that the facility maintain a temperature that is comfortable for the majority of patients. The dialysis facility must make reasonable accommodations for patients who are not comfortable at the temperature setting determined by the majority of patients. The facility has the option of allowing patients to bring a blanket to dialysis or providing freshly laundered blankets to the patients. Infection control procedures must be

adhered to in either case. Often patients need a warm environment because of lowered body temperature during the dialysis process, and therefore, facilities should look to patients rather than staff to ascertain comfortable building temperatures.

In the emergency preparedness standard (proposed § 494.60(d)), we have proposed requirements that we believe are fundamental for a dialysis facility to prepare effectively for emergency situations. These requirements include: (1) Procedures for medical and non-medical emergencies; (2) staff and patient training; (3) facility emergency equipment; and (4) periodic evaluation of emergency plans. Existing § 405.2140(d) requires the facility to have written policies and procedures that specifically define the handling of emergencies that may threaten the health and safety of patients. The existing regulations also stipulate that facility staff should be trained for any emergency or disaster, as part of their employment orientation.

We propose to clarify at § 494.60(d) that each dialysis facility must implement emergency preparedness procedures to manage potential medical and nonmedical emergencies that are likely to threaten the health or safety of facility patients, the staff, and the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The facility will need to identify which hazards are most likely to effect their facility, evaluate how to minimize risks, and plan how to best protect patients in the event of an emergency, using an emergency management approach. We do not expect individual facilities to develop emergency plans for natural disasters that typically do not affect their geographic location. For example, facilities located in the Southeast would not typically need to develop emergency procedures for earthquakes. Facilities located in the central plains States, on the other hand, would need to be prepared for tornadoes. All facilities must plan for fire, care related emergencies, equipment and power failures, and interruption of the water supply, because these emergencies may occur regardless of a facility's geographic location.

In addition to having emergency procedures, a facility will need to plan ahead so that necessary information and tools are available to staff and patients. For example, a facility would need to have current patient telephone numbers, addresses, and transportation information available before an emergency happens rather then scrambling to update this kind of information during an emergency. As a resource in their movement toward an emergency management approach, dialysis facilities may want to use the ESRD facility emergency preparedness guidelines available from the ESRD Networks.

We propose to maintain the existing requirement that a facility train each staff member on the actions required for different medical and nonmedical emergencies. The existing conditions for coverage require that emergency preparedness procedures be reviewed and tested at least annually and revised as necessary. Also, all personnel must be knowledgeable and trained in their respective roles in emergency situations. We are proposing that staff training must be evaluated at least annually and that staff must demonstrate knowledge of emergency procedures. This requirement is designed to ensure the safety and security of both the patients and the staff. We propose also to require that the facility provide periodic training to patients and staff. Patients routinely treated in dialysis units are at risk for medical emergencies. As a result, standard medical practice dictates that the facility must have trained personnel, drugs, and emergency equipment available to adequately support patients until an Emergency Medical System (EMS) unit responds to the facility.

We are proposing at § 494.60(d)(1)(ii) that staff must maintain current cardiopulmonary resuscitation (CPR) certification. This is the standard practice in United States dialysis facilities. We have not prescribed the type or number of staff who must maintain CPR certification but at a minimum, the patient care staff must maintain current CPR certification. In this instance, patient care staff are staff who routinely provide direct medical care to patients in the dialysis unit.

We would maintain the standard in the existing regulation (§ 405.2140(d)(5)) that the facility provides appropriate training to patients, so that they know the facility's emergency procedures, since they may need to take steps to protect themselves during an emergency. Dialysis patients need to be informed on what to do, where to go, whom to contact from home, and how to disconnect themselves from dialysis equipment if an emergency occurs.

The existing text in § 405.2140(d)(3) requires that the facility have available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment. We propose to maintain this requirement, but we want to eliminate the confusion regarding the meaning of ''fully equipped.'' We propose to define the minimum emergency equipment that must be on the premises and immediately available as ''oxygen, airways, suction, artificial resuscitator ventilation bag, defibrillator, and emergency drugs.'' We propose to specifically require defibrillators. Automated external defibrillators (AEDs), in particular, have been shown to save lives in a variety of settings, most notably aboard airlines and in airports. One Seattle study (Arch Intern Med. 2001;161:1509–1512 available at *http://www.ARCHINTERNMED.com*) identified dialysis centers as having a relatively high incidence of cardiac arrest (≥ 0.746 per practice annually). In the 9 dialysis facilities studied there were 47 cardiac arrests over a 7-year period. Approximately 56 percent, or 26 patients, had ventricular fibrillation and may have benefited from use of an AED. The authors of this study presented their findings to the nine dialysis centers and all nine agreed to equip their centers with AEDs and to train their staff in the use of AEDs.

The key to saving a life is getting the defibrillator on the patient as soon as possible. The AED allows dialysis facility staff to defibrillate a patient without requiring the immediate presence of a physician. According to the American College of Emergency Physicians (*www.acep.org/1,2891,0.html*), when a person suffers a sudden cardiac arrest, the chance of survival decreases by 7 to 10 percent for each minute that passes without defibrillation. The very real potential for saved lives supports the financial investment in an AED. The cost of an AED is approximately $2,000 to $3,000. Some units have already voluntarily purchased AEDs. Very small units (for example, units with two hemodialysis stations) may find the purchase of an AED to be a heavy financial burden. We are soliciting comments on whether small, predominantly rural dialysis facilities should receive special consideration and possibly an exemption from the defibrillator requirement. We propose that the dialysis nursing staff must be trained on the proper use of emergency equipment and emergency drugs. Staff could be trained on the use of an AED in conjunction with the CPR training. Having the right equipment at the time of an emergency is only useful when staff is well versed in how to effectively use it. In addition, the facility must have

a plan to obtain EMS assistance when needed.

We are proposing to require a defibrillator without specifying an AED due to the fact that some dialysis units already have access to a defibrillator. Hospital-based dialysis units, in particular, may have immediate physician availability built into the hospital-wide cardiac resuscitation plan. This reduces the financial burden of the proposed defibrillator requirement.

We are proposing to maintain the requirement that facilities conduct reviews of their emergency and disaster plans to ensure that facilities appropriately respond to the situations and needs that may arise from a variety of emergencies, medical and nonmedical. We are proposing in § 494.60(d)(3)(ii) that facilities review their emergency and disaster plans at least annually. Drill and emergency episodes often reveal a weakness or flaw in the design of the emergency plan. An annual update will allow such flaws or potential problems to be identified and corrected.

Existing § 405.2140(b)(3) specifies that the facility have a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made. We propose to delete this requirement because we believe this is not a physical environment issue. It is important that patients are appropriately monitored during the dialysis session. However, monitoring is most effectively done through interaction between the patients and the staff in the dialysis area and not from a monitoring station.

We believe that existing § 405.2140(b)(5) is another process-oriented requirement, and we propose to delete this requirement. This requirement states that facilities using central batch processing must make arrangements to meet the needs of patients with special dialysis solutions. The Patient plan of care condition, proposed § 494.90, would require the dialysis facility to implement the care plan and make arrangements to meet the individual requirements of each patient regardless of whether those needs are related to special dialysis solutions or other medically necessary supplies or equipment.

The existing emergency preparedness standard (§ 405.2140(d)) enumerates the facility physical emergency management procedures but provides minimal standards for the procedures that must be followed during a fire. We propose to strengthen the section governing fire safety to provide greater detail regarding the appropriate procedures that must be followed.

We are proposing at § 494.60(e) to adopt the 2000 edition of the National Fire Protection Association's (NFPA) Life Safety Code (LSC). The LSC is a compilation of fire safety requirements for new and existing buildings and is updated and published every 3 years by the NPFA, a private, non-profit organization dedicated to reducing loss of life due to fire.

The Medicare and Medicaid conditions of participation have historically incorporated by reference these requirements along with Secretarial waiver authority. The statutory basis for incorporating NFPA's LSC for ESRD facilities falls under the Secretary's general rulemaking authority.

The 2000 edition of the LSC is divided into several occupancy chapters including a business chapter, educational chapters, ambulatory health care occupancy chapters, and health care occupancy chapters. The business occupancy chapter pertains to clinics and offices. The educational occupancy chapters pertain to schools and day care centers. The health care occupancy chapters pertain to inpatient health care facilities (for example, hospitals, nursing homes). Finally, the ambulatory health care occupancy chapters pertain to facilities that provide outpatient medical treatment that may render the patient temporarily incapable of self-preservation (for example, critical access hospitals, dialysis centers).

The *NFPA LSC Handbook* specifically designates Chapter 20 and Chapter 21 for outpatient dialysis services. We propose to adopt, as recommended by the NFPA LSC, Chapter 20 (that is, new ambulatory health care occupancy buildings) and Chapter 21 (that is, existing ambulatory health care occupancy buildings) of the 2000 edition of the LSC for all outpatient dialysis facilities regardless of size.

The LSC classifies dialysis facilities as ambulatory health care occupancies because the treatment is not a routine medical visit to a doctor's office but rather a procedure that may hinder the patient from self-preservation in the event of an emergency or fire. Incapability of self-preservation might be the result of the use of general anesthesia or a treatment such as dialysis. Dialysis patients are not as mobile as a person working or visiting an office building or health clinic but more mobile than patients being treated in an inpatient health care facility, such as a hospital or nursing home. Chapters 20 and 21 give a level of safety from fire that is greater than the typical business occupancy but less than a health care occupancy such as a hospital or nursing home.

Under our proposal, an outpatient dialysis facility would comply with the business occupancy provisions in Chapters 38 (that is, the new business occupancies) and 39 (that is, existing business occupancies) with the additional provisions contained within Chapters 20 and 21. Where there may be a conflict between the business occupancy chapter and the ambulatory health care occupancy chapter, the more stringent requirements would apply (LSC sections 20.1.1.1.2 and 21.1.1.1.2). The requirements of Chapters 20 and 21 are described below.

Chapter 20.1.2.1 and Chapter 21.1.2.1 require 1-hour fire separation between different occupancies or tenants in a multi-tenant building. We believe most dialysis facilities currently meet this requirement because most State building codes already require this provision.

Chapters 20.2.4 and 21.2.4 require that there be at least two emergency exits. Emergency lighting is required by Chapters 20.2.9.1 and 21.2.9.1 to ensure that the center is lighted and that egress paths are illuminated to allow movement during an emergency.

Chapters 20.2.9.2 and 21.2.9.2 require an essential electrical system. This provision does not apply to dialysis facilities because dialysis equipment is not life-support equipment under the Life Safety Code.

Chapters 20.3.4.4 and 21.3.4.4 require the fire alarm system to provide automatic notification of a fire to emergency forces. This is of great importance for the protection of patients. Any delay in the notification of fire and rescue personnel could adversely impact the health and safety of patients and expose them to a fire, smoke, or toxic gases created by the fire.

Chapters 20.3.7 and 21.3.7 pertain to smoke compartmentation, otherwise known as subdivision of building space. Section 3.7 of Chapters 20 and 21 apply to any dialysis facility that is larger than 5,000 square feet (or 10,000 square feet for facilities with sprinklers). We believe most dialysis facilities will fall within the exceptions outlined in this provision. If a dialysis facility is smaller that 5,000 square feet and protected by an approved, supervised sprinkler system, then section 3.7 of Chapters 20 and 21 do not apply.

Section 7 of Chapters 20 and 21 specify procedures to assist outpatient dialysis facilities in providing fire safety. Section 7.1 of Chapters 20 and 21 propose evacuation plans and fire exit drills and require staff to practice the

procedures outlined in the dialysis facilities written emergency plans. Section 7.1 of Chapters 20 and 21 are appropriate for outpatient dialysis facilities because there is a possibility a dialysis patient could lose blood or suffer unnecessary risks if the patient were removed from the dialysis machine during a fire drill. We believe that requiring a dialysis facility to stop dialysis treatment and evacuate all dialysis patients during a fire drill is an unnecessary procedure that could jeopardize the dialysis patient's health and safety. Annex A, Explanatory Material to the 2000 NFPA LSC provides guidance for conducting fire drills when it is inexpedient and impractical to move patients during a fire drill. Many health care occupancies conduct fire drills by choosing the location of the simulated emergency in advance; practicing the movement of simulated patients or empty wheelchairs to adjacent safe areas, and ensuring that staff have the efficiency, knowledge, and response capability to implement the facility's fire emergency plan. Surveyors may determine whether this standard was met by checking a dialysis facility's records and interviewing staff to verify that the emergency and fire drills were conducted not less than once in each 3-month period and that staff are very familiar with the procedures.

Section 7.1.1 in Chapters 20 and 21 also require that the dialysis facility prominently post its emergency plan. We expect the plan to include continuity of essential building operations in the event of an emergency. Electrical, water, fire protection, ventilation, and communications systems are some, but not all, areas a dialysis facility should consider in its disaster plan. A good reference, but not a requirement for developing an emergency plan for a dialysis facility, is the NFPA 99—Standard for Health Care Facilities, Chapter 11, Health Care Emergency Preparedness (NFPA, November 2001). Our intent in proposing the posting requirement is to ensure patients, staff and the public have the proper information to quickly evacuate in the event of an emergency.

The remaining provisions in section 7 of Chapters 20 and 21 include requirements for the procedures in case of fire (20.7.2 and 21.7.2); maintenance of exits (20.7.3 and 21.7.3); smoking regulations (20.7.4 and 21.7.4); furnishings, beddings, decorations (20.7.5 and 21.7.5); maintenance and testing of life safety-related equipment (20.7.6 and 21.7.6); portable space heating devices (20.7.7 and 21.7.7); and construction, repair and improvement operation (20.7.9 and 21.7.9).

We recognize that for some dialysis facilities it would be extremely burdensome to adhere strictly to all of the LSC requirements. For example, older dialysis facilities or facilities leasing space in an office building may not be able to add sprinkler systems. We are proposing to retain our existing authority to waive specific provisions of the LSC on a case-by-case basis, further reducing the exposure to additional cost and burden for facilities with unique situations that can justify the application of waivers which we determine will not endanger the health and safety of patients. We propose that a waiver may be granted for a specific LSC requirement if: (1) We determine that the waiver would not adversely affect the patient/staff health and safety; and (2) we determine that it would impose an unreasonable hardship on the facility to meet a specific LSC requirement. A provider may request a waiver from its State Agency. The State Agency will review the request and make a recommendation to the appropriate CMS Regional Office. The CMS Regional Office will review the waiver request and the State Agency's recommendation and make a final decision on the waiver request. A waiver cannot be granted if patient safety is compromised in any way.

A State may also request that a State fire and safety code, imposed by State law, be applicable to all dialysis facilities rather than the LSC proposed in this rule. The State must submit the request to its CMS Regional Office and the Regional Office will forward the State's request to CMS Central office for a final determination.

V. Proposed Part 494 Subpart C (Patient Care)

A. Patients' Rights (§ 494.70)

[If you choose to comment on issues in this section please include the caption ''Patients' Rights'' at the beginning of your comment.]

The existing patients' rights condition, § 405.2138, requires that the facility's governing body adopt written patients' rights policies that are administered by the facility's chief executive officer (CEO). Sections 405.2138(a)(1) through (5) state that patients must be informed regarding the following: (1) Their rights and responsibilities; (2) services available at the facility and charges not covered; (3) their medical condition (by a physician); (4) the facility's reuse policies; and (5) their suitability for transplantation or home dialysis. Sections 405.2138(b)(1) and (2) afford patients the right to participate in planning their medical treatment; require that a patient may be transferred or discharged for only medical reasons or for the patient's or other patient's welfare or nonpayment of fees; and require that patients must be given advance notice to ensure an orderly transfer or discharge. Section 405.2138(c) states that patients must be treated with respect and dignity; § 405.2138(d) protects patient confidentiality of personal and medical records; and § 405.2138(e) states patients must be advised, encouraged, and assisted in exercising their rights to bring grievances (through a representative, if desired) without fear of discrimination or reprisal.

We are proposing to revise the provisions of this condition to include a number of changes, in keeping with our goals to reduce the Federal regulatory burden on dialysis facilities, eliminate unnecessary procedural requirements, and revise the conditions for coverage to be more outcome-oriented while protecting the basic rights of ESRD patients.

First, we are proposing at § 494.70 that the facility must inform patients (or their representatives) of their rights and responsibilities when they begin their treatment at the facility, and must also protect and provide for the exercise of those rights. We believe it is important to take steps to ensure that patients are fully and promptly informed of their rights. The existing regulatory language permits a facility an unspecified period of time to complete this activity. However, we believe that all dialysis patients must be informed of their rights and responsibilities when they begin their treatment, which is the standard practice in dialysis facilities, so they may exercise them from the beginning of their relationship with the facility.

Existing § 405.2138 provides a list of numerous persons to whom these written patient rights policies must be ''made available.'' The list includes patients and guardians, next of kin, sponsoring agencies, representative payees, and the public. Essentially, the facility must provide the list of patient rights to anyone who asks to see them. Rather than specifying a list of people to whom the patients' rights policies must be made available, we are proposing at § 494.70 that facilities inform the patients (or their representatives), and at § 494.70(c) that facilities post a copy of the patients' rights in a prominent location where it can easily be seen and read. This not only meets the objectives of the current list of disclosures, it also allows patients

to review their rights at any time during the course of their care at the dialysis facility.

Section 405.2138 also states that the CEO is responsible for the development of, and adherence to, procedures implementing the patients' rights policies. In § 494.70, we are proposing to change this requirement by holding the facility accountable for the outcome, which is to ensure that each patient's rights and the ability to exercise them are protected.

We are proposing to retain the patients' rights enumerated in § 405.2138(a)(1) through (a)(5) and include them in the proposed § 494.70(a).

Proposed § 494.70(a)(1) requires the dialysis facility to inform patients of their right to be treated with respect, dignity, and recognition of their individuality and personal needs as well as sensitivity to the patients' psychosocial needs and ability to cope with ESRD.

Proposed § 494.70(a)(2) requires a dialysis facility to provide information to patients in an understandable manner. The existing requirement at § 405.2138(c) requires dialysis facilities to provide translators ''where a significant number of patients exhibit language barriers.'' Presumably, under this existing requirement, if a single patient has language difficulty, the facility does not need to act to address this patient's needs. We are proposing to modify this requirement. Since written information is not required, the dialysis facility has the flexibility to decide the best vehicle for providing information to patients. We believe this more outcome-oriented requirement provides a facility with the latitude to devise its own means to ensure the outcome is met.

Proposed §§ 494.70(a)(3) and (4) would require a dialysis facility to inform patients regarding privacy and confidentiality, and also expands those rights to include specific references to privacy and confidentiality in all aspects of the patient's treatment as well as the patient's medical records. These requirements include existing provisions from § 405.2138(c) and (d). Staff should be instructed that any discussions with dialysis patients or relatives regarding treatment, the patient care plan, and medical conditions should be held in private and kept confidential. There should be reasonable precautions to keep both written and verbal patient information private. Staff should be aware of the need to speak at a volume and at a proximity to patients such that privacy is reasonably protected. Facility staff must make efforts to protect patient information and physical privacy. While recognizing the patient's right to privacy and confidentiality, we are not necessarily advocating physical barriers in the dialysis clinical area that provide patient privacy because patients should be in view of staff at all times during treatment to ensure safety. However, in situations when there is patient body exposure during therapy, the staff should be instructed to provide temporary screens, curtains, or blankets.

We are proposing at § 494.70(a)(5) to retain the existing requirement under § 405.2138(b)(1) that describes the right of patients to participate in the planning of their medical treatment and to refuse to participate in experimental research (or any part of their care). Section 494.70(a)(5) requires a facility to inform patients regarding their right to participate in all aspects of their care. Although we recognize that a facility cannot require its patients to participate in the care process, we expect the facility to work closely with patients and encourage patient participation to ensure that a care plan is developed that is suitable to the needs and concerns of both the patient and staff. The facility should notify patients in advance, if possible, of any changes in the treatment plan recommended by the physician and the basis for the changes. The facility should also encourage patients to disclose any concerns they may have with the proposed changes.

Proposed § 494.70(a)(5) would also require the facility to inform patients of the right to establish an advance directive. Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions. Advance directives include written documents including living wills and durable powers of attorney for health care, as recognized by State law.

Congress passed section 4206 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) to ensure that patients receive information regarding their right to execute or not to execute advance directives. While the OBRA 1990 requires hospitals, skilled nursing facilities, HHAs, managed care plans, and hospice programs participating in the Medicare program to establish and maintain written policies and procedures regarding advance directives, it does not specifically mention dialysis facilities.

In proposing to add advance directives to the patients' rights condition for coverage we took several factors into consideration. First is the chronic nature of ESRD. Kidney impairment is irreversible and permanent, and a regular course of dialysis or transplantation is essential to maintain life. In addition, we considered the amount of time a patient spends in the dialysis unit, and also the rapidly changing demographics of the ESRD patient population. The average age of the ESRD patient population is increasing annually. Elderly ESRD patients now comprise a large percentage of the total ESRD patient population. Data compiled by the United States Renal Data System, from 1990 to 2001, shows the following rate of new cases of ESRD for patients 65 years of age and older:

Age (in years)	Year											
	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
65–69	7,177	7,982	8,597	8,895	9,852	9,643	10,390	10,829	11,078	11,225	11,415	11,545
70–74	6,159	7,260	8,093	8,533	9,664	9,678	10,753	11,248	11,648	12,005	12,276	12,367
75–79	4,587	5,367	5,997	6,293	7,243	7,404	8,481	9,339	10,133	11,170	11,407	11,408
80–84	2,386	2,754	3,228	3,427	4,051	4,290	4,959	5,725	6,125	6,785	7,349	7,477
85+	961	1,113	1,277	1,481	1,659	1,833	2,248	2,598	3,110	3,587	3,870	4,146

The emergence of an older, sicker ESRD patient population has motivated the Renal Physicians Association (RPA) and the NKF to develop guidelines for implementation of advance directives in dialysis facilities, and we are encouraging dialysis facilities to adopt voluntary consensus guidelines for advance directives. The guidelines can be obtained through the NKF's Web site at: *http://www.kidneyva.org/public_ed/orderforms.pdf* and through the RPA

Web site at *http://www.renalmd.org/publications/index.cfm.*

After taking these factors into account, we believe it is prudent to consider adding advance directives as a requirement in the patients' rights condition of this proposed rule.

Existing § 405.2138(a)(5) requires that patients be informed of their suitability for transplantation or home dialysis. We have strengthened this requirement at § 494.70(a)(6) by proposing that patients be informed about alternative treatment modalities by requiring dialysis facilities to address all treatment choices. The treatment modality selected may directly affect the quality of life for dialysis patients. This choice is a very personal one, with important implications for how likely the patient is to be rehabilitated to the highest possible level. To assist dialysis patients in achieving the optimal quality of life, patients need education about each modality and must have access to the widest array of treatment choices possible.

For example, a successful kidney transplant is the most desirable treatment for many ESRD patients and facilities should make every effort to both educate and inform patients regarding the transplantation option. Also, forms of dialysis that can be performed at home have been shown to have a positive influence on the patient's quality of life. Home dialysis affords patients' control over scheduling and setting, and it can be done in comfortable, familiar surroundings. Also, home dialysis is generally perceived to be less disruptive to family life and employment. We propose to require that a facility inform patients about all available treatment modalities and settings, so patients can make an informed decision regarding the most appropriate course of treatment that meets their needs.

Open communication between the facility staff and the patient and patient access to treatment information are vital tools for enhancing the patient's participation in his or her coordinated care planning. Proposed § 494.70(a)(7) requires that patients be informed of the facility's patient care policies, including its patient isolation policies.

Proposed §§ 494.70(a)(8) through (10) retain existing requirements in § 405.2138(a)(2) through (4) that patients be fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers; be informed by a physician regarding his or her own medical condition unless contraindicated; and be informed of services available in the facility and charges not covered by Medicare.

Proposed § 494.70(a)(11) would require that patients be informed of the right to receive the necessary services outlined in the patient plan of care in proposed § 494.90. The importance of the patient plan of care is discussed in section V.C. of this preamble.

Proposed § 494.70(a)(12) would retain the existing requirement at § 405.2138(a)(1) that patients be informed of the rules and expectations of the facility regarding patient conduct and responsibilities. The success of the dialysis treatment is as contingent upon patients adhering to their responsibilities as it is upon other important factors. There is a discussion of the dialysis facility's responsibility regarding disruptive and difficult patients in section VI.E.9. of this preamble.

Proposed § 494.70(a)(13) would require facilities to inform patients regarding the facility's internal grievance process and their right to express grievances against the facility using the internal grievance process through a representative chosen by the patient (if so desired).

Proposed § 494.70(a)(14) strengthens the existing requirement for facilities to inform patients regarding the various external grievance mechanisms available to them, including how to contact the ESRD network and the State survey agency, and how to file external grievances without reprisal or denial of services, through a representative chosen by the patient or anonymously (if so desired). We believe that patients must be made aware of every grievance option available to them, including, at a minimum, contacting the two entities with the statutory responsibility under Federal law for addressing patient grievances (that is, the ESRD networks and the State survey agencies).

In proposed §§ 494.70(b)(1) and (2), we would require a facility to inform patients regarding its transfer and discharge policies and provide 30 days notice in advance of reducing or terminating patient care services following the discharge and transfer procedure outlined in § 494.180(f). The facility would be exempt from the 30-day notification requirement in cases when there was an immediate threat to the health and safety of others. Proposed §§ 494.70(b)(1) and (b)(2) and the procedure outlined at § 494.180(f) have been proposed, in part, in response to the ''disruptive'' or ''challenging'' patient issue. Increasing numbers of staff and patient grievances presented to the ESRD networks and the State survey agencies involve allegations of disruptive behavior by patients and allegations of inappropriate patient discharges from facilities for noncompliance or disruptive behavior. We would not expect a patient to be involuntarily discharged from a dialysis facility for failure to follow the instructions of a facility staff member. However, it may be necessary to discharge a disruptive patient in order to protect the rights and safety of other patients in the facility, or to protect the safety of facility staff.

We believe that a dialysis facility has both the resources and a responsibility to make a good faith effort to work with every patient, including patients perceived to be disruptive or challenging, to provide the necessary assessment, training, knowledge, and motivation to facilitate good outcomes of care. This process begins when the facility interdisciplinary team performs the comprehensive patient assessment described in proposed § 494.80, with periodic reassessments as needed; continues through the care planning process described in proposed § 494.90; as well as the facility's quality assessment and performance improvement (QAPI) program described in proposed § 494.110. We believe the disruptive or challenging patient problem is multifaceted, and even conscientious assessments, care planning, and QAPI programs by a facility will not always be successful in mitigating the disruptive behavior of some patients. In those instances when good faith efforts by a facility have been unsuccessful and the facility has determined that it wants to discharge or transfer the patient, facilities must follow the procedure outlined in proposed § 494.180(f), and arrange to transfer or discharge the patient, as appropriate.

We also recognize there will be rare instances when a facility must act immediately to discharge a patient. Such instances could be, for example, when a patient physically harms or threatens other patients and staff, a patient who brings weapons or illegal drugs into a facility, or a patient who is verbally abusive and disruptive to such an extreme degree that the facility is unable to operate effectively. In those and comparable circumstances, we would propose to shorten the 30-day notification requirement. We are soliciting comments on the proposed §§ 494.70(b)(1) and (b)(2), as well as suggestions for addressing the disruptive or challenging patient issue in the proposed ESRD conditions.

If a patient chooses not to use a facility's internal grievance process, or when grievances cannot be resolved at the facility level, the patient may elect to register a grievance with the

appropriate ESRD network or make a complaint directly to the State survey agency at any time. We believe it is essential that we require that patients be informed of every grievance and complaint option currently available to them under the law.

Proposed § 494.70(c) would require dialysis facilities to prominently display a copy of the patients' rights as well as the telephone numbers for the appropriate ESRD network and State survey agency in order to afford patients the opportunity to contact either entity, if desired. Dialysis patients have the right to be advised of and to use grievance processes developed by the facility, the ESRD network and the State survey agency.

B. Patient Assessment (Proposed § 494.80)

The proposed patient assessment condition at § 494.80 underscores our belief that systematic patient assessment is essential to improving quality of care and patient outcomes. The information generated from the patient assessment is a vital tool for developing a patient's care plan and subsequent treatment. A comprehensive patient assessment allows the dialysis facility to monitor the patient's progress toward achieving the desired care outcomes and adjust the plan of care and treatment prescription as necessary.

The existing regulations in part 405 subpart U do not state that a patient will receive a comprehensive assessment. However, two sections of the existing regulations, §§ 405.2136(g)(1) and 405.2137(b)(1), provide a basis for a patient assessment. For example, § 405.2136(g)(1) holds the patient's physician responsible to prescribe a planned regimen of care, ''which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge.'' That section also states that such plans are made with the input of the professional personnel providing care to the patient. Existing § 405.2137(b)(1) states that a patient care plan ''reflects the psychological, social, and functional needs of the patient,'' and indicates ESRD and other care needed to achieve the long- and short-term treatment goals.

Therefore, while the existing regulations indicate that a specialized care plan must be developed based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs, it does not specify the criteria that a facility must include in a patient assessment. Over the past 25 years, research has improved our knowledge of the components important to assessing and treating the dialysis patient so that improvements in quality of life and morbidity and mortality rates have been achieved.

We believe that a comprehensive patient assessment that includes clinical interaction with the patient is a prerequisite for the delivery of quality care and is the basis for determining a patient's functional status and identifying the services necessary to address the patient's needs. Accurate and accessible patient information generated from the comprehensive assessment is critical to the development of a successful patient care plan and the achievement of desired patient outcomes.

We do not believe that expanding the existing requirements in this proposed condition will impose any additional burden on facilities. Rather, we believe quality-oriented facilities already routinely perform comprehensive patient assessments upon initiating treatment. Further, we believe most facilities already have this information in different parts of the medical record since an appropriate and effective treatment plan cannot be developed without an initial assessment.

We are proposing at § 494.80 to add a patient assessment condition for coverage that would make the ESRD facility, through the patient's interdisciplinary team, responsible for providing each of its patients with an individualized and comprehensive assessment of his or her needs. The members of the interdisciplinary team (see proposed § 494.10) would include the patient (if he or she chooses), a registered nurse, a physician, a social worker, and a registered dietitian. With the team concept, the goal is to obtain input from each designated health professional as well as from the patient to develop an assessment that identifies the patient's needs and allows for planning for necessary services. The proposed team members represent vital components of the patient's medical treatment and psychosocial development. These professionals are also key to a successful transition to dialysis as well as to maintaining the patient's quality of life. An assessment that involves the patient as a key member of the interdisciplinary team is important to the successful delivery of service and the patient's adherence to the program.

In proposed § 494.80(a), we list the assessment criteria. The minimum proposed elements of a patient's assessment include the following:

- Evaluation of current health status, including comorbid conditions and medical condition.
- Evaluation of the appropriateness of the dialysis prescription, blood pressure control, and fluid management needs.
- Laboratory profile and medication history.
- Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of recombinant erythropoietin.
- Evaluation of factors associated with renal bone disease.
- Evaluation of nutritional status.
- Evaluation of psychosocial needs.
- Evaluation of dialysis access type and maintenance.
- Evaluation of the patient's ability, interests, preferences, and goals, including level of participation in the dialysis care process; modality and setting (for example, home dialysis, including home hemodialysis or peritoneal dialysis); and expectations for care outcomes.
- Evaluation of suitability for transplantation referral, based on criteria developed by the transplant surgeon at the transplant center that would receive such transplantation referral including the basis for referral or nonreferral.
- Evaluation of family and other support systems.
- Evaluation of current physical activity level.
- Evaluation of vocational and physical rehabilitation status and potential.

Other information to be included in the initial assessment would be determined by the interdisciplinary team based on the specific characteristics and needs of the patient.

We recognize that inclusion of a minimum set of assessment criteria may appear to be inconsistent with our goal of eliminating unnecessarily prescriptive and process-oriented requirements. However, we believe it is appropriate and necessary for every patient assessment to focus not only on the patient's medical needs, but also on his or her psychosocial and rehabilitation needs. Further, these assessment criteria would assure that needed information would be available for the patient plan of care and the facility's quality assurance and performance improvement program.

We propose criteria for the frequency of assessment and reassessment of new patients in §§ 494.80(b)(1) and (2). A timely, comprehensive assessment is critical for planning patient care and achieving desired patient outcomes. We

believe this requirement, though process-oriented, is necessary to prevent harm to the patient. By permitting facilities 20 calendar days to complete assessments, we are providing a reasonable timeframe for every member of the team to assess the patient prior to development of the treatment plan.

We also recognize that patients who are new to dialysis need time to adjust and adapt to the treatment. Initially, patients may experience a great deal of anxiety while learning self-care skills, modifying their diet, changing their behavior, and perhaps dealing with access issues. The level of compliance with the renal regimen may be set by the time the person has been on dialysis for 4 to 6 months (Sciarini, pp. 299–305). Because of this period of adjustment, and the opportunity to establish the patient's adherence to the renal regimen, proposed § 494.80(b)(2) would require a follow-up comprehensive reassessment for new patients within 3 months after the completion of the initial comprehensive assessment. Three months was chosen so that the window of opportunity for establishing adherence to the renal regimen by a new patient is not missed. We recognize the additional burden this 3-month reassessment will place on the interdisciplinary team. However, an updated plan of care and the attention to the patient's adjustment to the renal regimen may prevent problems in the coming months. The reassessment also ensures the continued accuracy and effectiveness of the treatment regimen.

Existing § 405.2136(g) states that the physician responsible for the patient's medical supervision evaluates the patient's needs and prescribes a planned regimen of care for dialysis. Sections 494.80(c)(1) and (2) propose a schedule for the assessment of the treatment prescription for hemodialysis and peritoneal dialysis patients. Studies indicate that ESRD patient mortality is lower when patients receive sufficient dialysis treatments. There has been considerable research recently indicating that the dose of dialysis is an important determinant of survival and morbidity of patients on hemodialysis ((Held, pp.871–875); (Owen, pp.1001–1006); (Parker, pp.981–989); and (Parker, pp.670–680)). The delivered dose of dialysis (Kt/V or an equivalent measure) indicates how well the dialysis treatment is working. Kt/V is the dialyzer clearance of urea (K) times the time of treatment (t), divided by the volume of distribution of urea (V), which yields a dimensionless value. Adequacy of dialysis clinical practice guidelines are available in the National Kidney Foundation's Kidney Disease Quality Initiative (NKF–K/DOQI). As previously discussed in this preamble, the NKF–K/DOQI has established clinical practice guidelines for ESRD patients. This systematic, evidence-based approach to developing guidelines used focus workgroups to identify target issues and conducted extensive literature searches to extract relevant clinical study reports for each target issue. Clinical practice guidelines were derived from this information. The guidelines are available for public review and comment, and they continue to be reviewed. Health care professionals and providers, ESRD networks, managed care groups, industry, government, patient associations and individuals are invited to provide comments to the NKF–K/DOQI workgroups. These comments are reviewed and when appropriate, incorporated in future editions.

An important initiative of this project is the development of guidelines for the dose of dialysis, including standard methodology(ies) for measuring the dialysis dosage.

To ensure that ESRD patients receive sufficient dialysis, the delivered dose of dialysis needs to be measured. Therefore, in keeping with the NKF's K/DOQI clinical practice guidelines, we propose in § 494.80(c) to specify that the delivered dose of dialysis for the patient's hemodialysis treatment prescription must be measured at least monthly, and the patient's peritoneal dialysis treatment prescription should be assessed at least every 4 months. More frequent monitoring may be necessary for new dialysis patients or when the dialysis prescription is changed. Less frequent monitoring of the adequacy of dialysis may compromise the timeliness with which deficiencies in the delivered dose of dialysis are identified and hence may delay implementation of corrective action.

In §§ 494.80(d)(1) and (2) we propose patient reassessment timeframes for both stable and unstable patients with respect to the standards specified in §§ 494.80(a)(1) through (a)(13). The comprehensive assessment process can be seen as part of a cycle. Through the use of the patient assessment, accurate and timely patient information is reflected in the plan of care. As the assessment changes, the plan of care must be revised accordingly. If the patient's condition is stable, we propose in § 494.80(d)(1) that the facility must perform comprehensive reassessments at least annually, which assures that patients are receiving a continuing program of care that meets their needs. This proposed timeframe minimizes the facility burden because the existing § 405.2137(b)(4) requires care plan review every 6 months for stable patients. If the patient is unstable, we are proposing in § 494.80(d)(2) to require a monthly reassessment, to allow for the update of the plan of care. Existing § 405.2137(b)(4) also requires a monthly review of the care plan for patients whose medical condition has not become stabilized. In proposed §§ 494.80 (d)(2)(i) through (d)(2)(iv), we added criteria to specify at a minimum, which patients may be considered to be unstable patients. These criteria include extended or frequent hospitalizations, marked deterioration in health status, a significant change in psychosocial needs, or poor nutritional status, with unmanaged anemia and inadequate dialysis. Extremely frail patients may need monthly reassessments. However, we are not proposing a specific requirement for monthly reassessments for frail patients because we believe this type of requirement would be too prescriptive and limit the flexibility of dialysis facilities to make clinical determinations on a case-by-case basis.

The renal community has been unable to reach a consensus regarding the optimum frequency of assessments. Some believe that the proposed time periods create a strain on facilities, while others have encouraged us to propose more stringent timeframes. Because of the wide range of opinion in this matter, we are specifically soliciting public comments on whether the proposed 3-month timeframe for reassessment of new patients is reasonable and consistent with meeting the patient's needs.

C. Patient Plan of Care (Proposed § 494.90)

[If you choose to comment on issues in this section please include the caption ''Plan of Care'' at the beginning of your comments.]

The patient assessment serves as the basis for the patient plan of care. Existing § 405.2137 contains a large number of prescriptive requirements for the development of patient care plans. These requirements specify that there needs to be a patient long-term program and a patient care plan.

The patient long-term program described in existing §§ 405.2137(a)(1) through (a)(4) relates to the selection of a suitable treatment modality and treatment setting by the treatment team. It also requires active participation by the physician director in the unit where the patient is being treated, a formal review of the written long-term plan by the team every 12 months, patient involvement in the plan's development,

and a requirement to send the plan to the receiving facility within 1 day of an interfacility transfer.

The patient care plan in existing § 405.2137(b) requires a written care plan based on the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs. Additional requirements in existing §§ 405.2137(b)(1) through (b)(7) include a personalized care plan reflecting the patient's needs, a care plan developed by a professional team (including the physician responsible for the patient's care), the involvement of the patient (or the patient's parent or legal guardian), a monthly review for unstable patients, a 6 month review for stable patients, sending the plan to the receiving facility within one day for interfacility transfers, periodic monitoring of home dialysis patients, and monitoring for home dialysis patients who use erythropoietin.

In accordance with our goal of reducing Federal regulatory burden, we have simplified the proposed patient care plan condition (§ 494.90) by eliminating the separate requirement for a patient long-term program.

We propose to retain some of the existing requirements of § 405.2137 in the patient assessment condition (proposed § 494.80). We believe that the patient assessment and patient care planning processes are inextricably linked. That is, each patient assessment must be followed with a review and revision, if necessary, of the patient's plan of care.

The comprehensive plan of care is an individualized program that ensures that each dialysis patient receives personalized and appropriate patient care within the selected modality and setting of treatment. In proposed § 494.90 we would specify that the patient's plan of care must include measurable and expected outcomes and estimated timetables to meet the patient's medical and psychosocial needs as identified in the initial and subsequent comprehensive assessments. This section would also specify that the patient's plan of care must address all the services that are to be furnished to achieve and maintain the expected outcomes of care.

Existing §§ 405.2137(a)(1) and 405.2137(b)(2) specify the composition of the professional team responsible for the preparation of the long-term and the patient care plans. The facility's professional team currently writes a patient long-term program and a short-term care plan. However, proposed § 494.90 would require that a single patient plan of care be developed and this plan would address all of the patient's needs. We are proposing in § 494.90 to retain the existing requirement that the patient plan of care to be developed by the interdisciplinary team. Although we would retain the existing §§ 405.2137 (a)(1) and (2), we have chosen to use the term ''interdisciplinary team.'' The term ''interdisciplinary team'' is defined § 494.10 and described in § 494.80. In § 494.80, we are proposing that the interdisciplinary team consist of, at a minimum, the patient (if he or she desires) or his/her designee, a registered nurse, a nephrologist or physician treating the patient for ESRD, a social worker, and a dietitian. We are using the term ''interdisciplinary team'' instead of ''professional team'' because the term ''interdisciplinary team'' is commonly used in health care settings, including dialysis facilities.

Although existing § 405.2137(a)(1) specifies a transplant surgeon as a member of the professional team, we did not include a transplant surgeon as a member of the interdisciplinary team as defined in proposed § 494.10 and described in proposed § 494.80. We believe all eligible ESRD patients must be referred for transplantation. However, it may not be reasonable to have transplant surgeons sign every care plan. The existing interpretive guidelines for surveyors (Survey Procedures and Interpretive Guidelines for End-Stage Renal Disease Facilities, Appendix H, State Operations Manual) allow a transplant surgeon's designee, who could be a transplant coordinator or the treating nephrologist, to screen patients in the long-term care plan process (DHHS/CMS, April 1995). The designee would have to use screening criteria developed by the transplant surgeon. Because not every patient is medically suited for a transplant, we believe the transplant surgeon need not be involved with the team unless a possible candidate has been identified. We are proposing that the dialysis facility must have inclusion/exclusion criteria, defined by the transplant surgeon based at the transplant center that would receive the transplantation referral, to use in the evaluation of patients for transplant referral. Therefore, we propose to delete the requirement that a transplant surgeon directly sign the care plan. We believe transplant referral tracking must be part of the comprehensive plan of care condition (*see* § 494.90(c)), and we have also proposed to strengthen this requirement in the patient assessment (§ 494.80) and patient's rights (§ 494.70) conditions. We are soliciting comment on the appropriate role of the transplant surgeon in developing the patient plan of care.

Existing § 405.2137(a)(1) also requires that the facility medical director and a physician from a facility that offers home dialysis (if the patient's present facility does not) be included in the team that develops the patient's long-term program. While we believe the involvement of these physicians would be valuable in most cases, we recognize that there are situations when the services of these physicians may not be needed. Thus, in keeping with our goal of eliminating unnecessary process requirements, proposed § 494.10 specifies the definition of ''interdisciplinary team'' without including the facility medical director and the home dialysis physician. Nonetheless, we encourage facilities to expand the interdisciplinary team to include as many health professionals as necessary to furnish the best care possible to their patients.

As required in existing § 405.2137 and in proposed § 494.10, a physician is part of the interdisciplinary team. We propose retention of this requirement because we believe the physician must play an integral role on the interdisciplinary team. The physician responsible for the patient's dialysis treatment works with the other team members to ensure the development of an appropriate care plan for the patient. We also expect the physician to see the patients and monitor their care.

Existing § 405.2137(b)(3) specifies that the patient may be involved in the development of the care plan and consideration is given to the patient's preferences. The patient's right to be informed about and participate within the interdisciplinary team is encompassed in proposed § 494.70(a)(5). The patient or his/her designee, if he or she desires, as a member of the interdisciplinary team, must collaborate to design a plan of care that enables the patient to reach his or her desired level of general health, activity, and quality of care. When a patient communicates his or her goals regarding their medical treatment, he or she plays a more active role in improving their quality of life. We have eliminated the phrase ''due consideration is given to [the patient's] preferences'' because we believe it implies the patient (or the patient's designee) is not an equal member of the team. Each patient must be given the opportunity to participate with the interdisciplinary team. However, we would not require them to do so in the proposed requirements because we recognize that some patients may not wish to participate in the team process. We are proposing that the patient or

designee must sign the plan of care to assure the patient is aware of treatment plans and goals regardless of whether the patient has opted to participate in the care planning team process.

The patient plan of care must include measurable and expected outcome targets or goals for each patient based on the individual patient's assessment. These outcome targets must allow the patient to achieve current evidence-based community-accepted standards. Currently, the K/DOQI clinical practice guidelines are the community-accepted standards for individual patient care and we expect ESRD facilities to reflect the current standards of care for dialysis adequacy and anemia management in the patient plan of care. As additional evidence-based community-accepted standards become evident, they could be targeted in the patient plan of care as well.

We propose that allowing the patient to achieve current evidence-based community-accepted standards for dialysis adequacy and anemia means (at § 494.90(a)(1)), that the patient plan of care should specify a minimum delivered threshold for Kt/V of at least 1.2 (single pool) for hemodialysis patients (NKF, Guideline 4); 1.7 (weekly) for continuous ambulatory peritoneal dialysis (NKF, Guideline 15); 2.1 (weekly) for continuous cycling peritoneal dialysis patients (NKF, Guideline 16); and 2.2 (quarterly) for intermittent peritoneal dialysis patients (NKF, Guideline 16). For anemia management (proposed § 494.90(a)(3)), the minimum specified threshold levels in the patient plan of care are: a hemoglobin level of 11 gm/dL or comparable hematocrit of at least 33 percent (NKF, Guideline 4).

There is significant correlation between achieving recommended NKF-K/DOQI values for the adequacy of dialysis and anemia management measures with positive outcomes in mortality, hospitalization, and/or quality of life. Thus, the advantages of assigning patient-level minimum targets and thresholds is that we would establish a process when patients whose values do not meet the criteria are evaluated for possible further intervention so that they can achieve values that are associated with better outcomes. It is understood that guidelines and standards, although evidence-based, are not appropriate for all patients in all situations. Thus these minimum thresholds serve as indicators for potential quality improvement activity.

We are proposing that outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based community-accepted standards.

However, we are soliciting public comments on this issue, and we will be guided by those comments in reaching a final determination on whether to require minimum threshold values for the patient plan of care as we develop the final rule for new ESRD conditions for coverage.

1. Development of the Patient Plan Of Care (Proposed § 494.90(a))

In developing this proposed rule, we determined that there is sufficient evidence to support the inclusion of minimum set of evaluative categories in the patient plan of care that have been shown by independent medical research to be important in achieving desirable patient outcomes. We are proposing (in § 494.90) that the patient plan of care must, at a minimum, address: (1) Dose of dialysis; (2) nutritional status; (3) anemia; (4) vascular access; (5) transplantation status; and (6) rehabilitation status. Each of these elements is discussed below.

a. Dose of Dialysis (Proposed § 494.90(a)(1))

There is a consensus in the renal community that adequacy of dialysis in terms of a Kt/V is an important clinical performance measure and the vast majority of dialysis facilities do use minimal target levels or goal levels or both to ensure delivery of quality care. We are proposing in § 494.90(a)(1) that the patient's interdisciplinary team assist and support the hemodialysis and peritoneal dialysis patient in achieving and maintaining an adequate dose of dialysis that meets evidence-based community-accepted standards as specified by the Secretary. We are soliciting comments on the possible use and appropriate minimum threshold values for the adequacy of dialysis.

b. Nutritional Status (Proposed § 494.90(a)(2))

Existing § 405.2163(d) states that the dietitian, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling on prescribed diets, and monitoring adherence and response to diets.

Our proposed requirement on nutrition at § 494.90(a)(2) would require the interdisciplinary team to provide the necessary care and services to achieve and sustain an effective nutritional status. Effective nutritional status encompasses acceptable levels of protein, calorie, and fluid intake as well as acceptable levels of nutrients in the blood. We did specify that one patient plan of care nutritional measure, the serum albumin (a marker of visceral protein stores), must be monitored on a monthly basis to reflect current standards of practice.

The National Institutes of Health (NIH), in its Consensus Conference Report entitled ''Morbidity and Mortality of Dialysis,'' identified nutritional status as an important indication of the renal patient's health (DHHS/NIH, pp.1–33). We recognize that nutrition plays an important role in the management of renal disease. However, we have found diverse opinions about using an objective measure as a clinical outcome measure for nutritional status. Potential clinical outcome measures of nutritional status include anthropometric measures, clinical signs of nutrient deficiency, urea kinetic modeling, prognostic nutrition indexing, and measurement of biochemical parameters. The NKF–K/DOQI clinical practice guidelines for Nutrition of Chronic Renal Failure (Guideline 1) state that, ''there is no single measure that provides a comprehensive indication of protein-energy nutritional status.'' (NKF, pp. S17.) NKF–K/DOQI guideline 3 further states that, ''serum albumin is a valid and clinically useful measure of protein-energy nutritional status in maintenance dialysis patients.'' (NKF, pp. S20.)

We invite comments on whether any additional specific nutritional outcome measures, such as other biochemical parameters of serum protein (total protein, transferrin, or prealbumin), or the protein catabolic rate or protein equivalent of total nitrogen appearance measure should be used as a patient plan of care outcome measure.

c. Anemia (Proposed § 494.90(a)(3))

Proposed § 494.90(a)(3) uses anemia, as measured by the hematocrit (or comparable hemoglobin) level, as a specified patient outcome. There is a consensus in the community that the use of hemoglobin, hematocrit or both to monitor anemia management are important clinical performance measures and the vast majority of dialysis facilities do use minimal target levels or goal levels or both for these measures to manage anemia in the dialysis patient. In § 494.90(a)(3) we propose that the patient's interdisciplinary team assist and support the hemodialysis and peritoneal dialysis patient in achieving and maintaining the expected hemoglobin/hematocrit level. The hemoglobin or hematocrit level must be measured at least monthly, as is the current standard practice. We are soliciting comments on

the possible use and appropriate minimum threshold values for anemia management.

Existing § 405.2163(g) address the patient's hematocrit or comparable hemoglobin level as a marker for the necessity for administering erythropoietin at home. The assessment criteria include: (1) Preselection monitoring (lab values and blood pressure); (2) hematocrit or comparable hemoglobin level less than 30 percent or medical justification for a higher hematocrit or comparable hemoglobin level; (3) a target hematocrit or comparable hemoglobin range for a patient receiving erythropoietin of 30 to 33 percent; and (4) the patient is under the care of a physician responsible for dialysis-related services. There are also additional process requirements. We are eliminating some of these process requirements and proposing that each patient be evaluated for anemia as specified in the patient assessment condition at § 494.80(a)(4). We are also proposing that any patient with a hematocrit of less than 33 percent or a hemoglobin of less than 11 gm/dL must be evaluated as a candidate for erythropoietin use. For home dialysis patients, we are proposing that the facility evaluate whether the patient can be trained to safely, aseptically and effectively administer erythropoietin, and store erythropoietin under refrigeration. The patient's response to erythropoietin, including blood pressure levels and the patient's utilization of iron stores, must be monitored on a routine basis.

Section 1881(b)(1)(C) of the Act specifies that the patient self-administering erythropoietin must be able to safely and effectively administer the drug in accordance with the applicable methods and standards established by the Secretary. Section 1861(s)(2)(O) of the Act states that Medicare will pay for erythropoietin as ''medical and other services'' if the patient self-administers the drug ''subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug. * * *'' Section 405.2163(g)(2) and (3) of the existing regulations specify the applicable methods as established by the Secretary. In keeping with our outcome-oriented focus, we are proposing to retain only those specific evaluation criteria that are clinically necessary and supported by the NKF–K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease, 2000 Update. Also, we are not proposing to retain all of the requirements in existing § 405.2137(b)(7) relating to the plan providing for monitoring home use of erythropoietin. We believe these requirements are unduly prescriptive and may not reflect the most appropriate items to monitor for each individual patient. We want to provide flexibility to a facility to develop its own criteria to monitor all patients who are using erythropoietin.

In § 494.90(a)(3) we are proposing to provide the facility with the flexibility to develop their own assessment and patient plan of care criteria for patients for whom the use of erythropoietin would be appropriate. In addition, we are proposing in § 494.90(a)(3) that a dialysis patient's response, including blood pressure and utilization of iron stores, to erythropoietin must be monitored on a routine basis. The patient plan of care should ensure that the patient is trained and is competent to safely, aseptically, and effectively administer the drug; provide for monitoring and safe refrigerated storage for home use of erythropoietin; and target appropriate hematocrit or hemoglobin levels.

d. Vascular Access (Proposed § 494.90(a)(4))

Our existing regulations do not contain any specific requirements pertaining to hemodialysis vascular access. We note that the hemodialysis procedure is dependent on the availability of a patent vascular access. According to data from the United States Renal Data System access failure is the second most frequent cause of hospitalization among ESRD patients. Access failure is also one of the significant contributors to hemodialysis patient morbidity. The costs of vascular access failure are also significant. In 1999 the total Medicare ESRD program expenditure for vascular graft failure was more than $97 million. Dialysis facilities may not have complete control over the type and placement of the access. However, it has been demonstrated that efforts to improve access patency can help to extend the life of an access. The NKF–K/DOQI provides vascular access clinical practice guidelines that address the importance of access monitoring and methods for improving the quality of patient care in this area (NKF, pp. S137–S181).

Therefore, we are proposing in § 494.90(a)(4) to include vascular access as a component of the patient plan of care with the following requirements for the interdisciplinary team:

- Evaluation of the hemodialysis patient for the appropriate vascular access type, taking into consideration co-morbid conditions and other risk factors.
- Support and assist the patient in achieving and maintaining vascular access patency.
- Routinely monitor the hemodialysis patient's vascular access to prevent access failure, including routine monitoring of artiovenous grafts and fistulae for stenosis.

e. Transplantation Status (Proposed § 494.90(a)(5))

Although we are proposing to remove the existing requirements for a separate long-term program from the conditions (*see* § 405.2137), we are proposing in § 494.90(a)(5) to retain the concept of transplant planning. Within the plan of care, the interdisciplinary team must address whether the patient is a transplant candidate and identify the plan for obtaining a transplant. The plan and the actions necessary to make the transplant a reality must be addressed in the plan of care. Necessary actions would include, for example, patient transplant referral for evaluation by a transplant center, communication with the transplant center, and monthly blood draws for antigen/antibody testing. We are soliciting public comment on whether the ''necessary actions'' listed above should be a requirement for dialysis facilities.

When the patient is not suitable for transplantation referral evaluation, the reason for nonreferral must be written in the patient's assessment and notated in the patient plan of care. The reason(s) for nonreferral must be consistent with the criteria developed by the prospective transplantation center and surgeon. In cases when the patient meets the transplantation criteria but declines referral, there must be documentation in the patient plan of care that the patient has made an informed decision to decline renal transplantation.

f. Rehabilitation Status (Proposed § 494.90(a)(6))

Existing § 405.2163 includes rehabilitation-related activities under the minimal service requirements for social services. Advances in technology and pharmacology have offered the possibility of significant improvements in the well-being of dialysis patients. More efficient dialysis equipment, the development of the synthetic hormone erythropoietin and active vitamin D, for example, represent important breakthroughs in quality-of-life areas. However, despite this improved potential for restoration, it is generally acknowledged that renal rehabilitation has not yet been addressed nationally in

a consistent, integrated fashion. Therefore, we are proposing to focus on rehabilitation outcomes through this requirement.

For dialysis patients, rehabilitation means restoring the mind and body to encourage the individual to maintain as full and active a life as possible. The Life Options Rehabilitation Advisory Council has defined the ideal process of rehabilitation for a dialysis patient as a coordinated program of adequate dialysis, education, counseling, and dietary regimens designed to maximize the vocational potential, functional status, and quality of life of dialysis patients (The Life Options Rehabilitation Advisory Council, p. 20). The ultimate goals of renal rehabilitation include employment for those who can work, enhanced physical fitness, increased individual control over the effects of kidney disease and dialysis, and the ability to maintain as active a lifestyle as possible. Many renal professionals equate successful renal rehabilitation with employment, in part because employment can be readily measured and documented, but factors other than employment must be examined in a complete discussion of rehabilitation or functional status of dialysis patients.

Comprehensive rehabilitation efforts can make the difference between an acceptable quality of life and mere existence. The improved overall health and outlook of successfully rehabilitated patients may have positive cost implications as well (Stewart, pp. 907–913). Patients who are rehabilitated to the point of employment may be able to offset Medicare costs, subject to Part 411, Subpart F, of our rules, if they have health insurance through their employment that would cover the costs of ESRD treatment in place of Medicare. Patients whose physical health improves to the point when they can manage self-care activities may allow an adult caregiver to re-enter the workforce. Even patients who cannot care for themselves, but whose outlook and quality of life are improved, can experience positive health consequences that reduce costs; thus keeping patients at home rather than in nursing homes decreases the costs of care as well. And costs notwithstanding, the achievement of these improvements in the patient's condition is inherently invaluable. (The Life Options Rehabilitation Advisory Council, p. 20).

Rehabilitation cannot be ''done to'' the patient. Active patient participation in rehabilitation is key to the success of any rehabilitation effort. Facility staff must inform and educate patients that their participation in rehabilitation programs is critical to their well being, ongoing treatment, and attainment of a successful adjustment to their condition. The patient's responsibility to participate in rehabilitation efforts is no less essential than her or his compliance with any aspect of the management of her or his care.

In this proposed rule, we are separating the rehabilitation requirements (proposed § 494.90(a)(6)) into a distinct plan of care category, and we are implicitly extending the definition of rehabilitation to include education. We have chosen to include rehabilitation as a specific category because we want the interdisciplinary team to focus on providing patients with the opportunity and the education for rehabilitation. In addition, staff attitudes about rehabilitation may have a correlation to patients' own attitudes about their potential to regain functional status.

It is not sufficient for facility staff to merely provide information about rehabilitation to patients. Rather, the essential role of rehabilitation in the treatment and recovery process must be continuously conveyed to patients and their families. To that end, the proposed requirement for rehabilitation status requires that the interdisciplinary team play a critical role in supporting the patient and advising the patient on his or her rehabilitative efforts. Specifically, the interdisciplinary team must provide the necessary care and services for the patient to achieve and maintain an appropriate level of productive activity, including vocational, that permits the patient to resume, to the extent feasible, activities engaged in prior to kidney failure. As part of this requirement, rehabilitation should be included in the patient's treatment prescription; the patient's involvement in rehabilitation activities should be incorporated in patient education materials; and facility patient support groups focusing on rehabilitation activities could be offered. Under this condition, facility staff should encourage and educate patients on the benefits of rehabilitation. The importance of rehabilitation as part of the treatment and recovery process must be conveyed, so patients come to recognize it as a benefit to themselves. The team must reinforce activities that lead to successful rehabilitation. The interdisciplinary team must provide care and services to younger patients to enhance the possibility of a successful transition to adult life and responsibilities. Although rehabilitation services may not be needed by pediatric patients, there may be educational needs and developmental needs that the interdisciplinary team must consider when writing and implementing the patient plan of care.

This proposed condition does not hold facilities accountable for rehabilitative outcomes that are beyond their control; instead, this proposed standard requires that interdisciplinary team staff use a combination of medical treatment, education, counseling, and dietary regimens to maximize dialysis patients' rehabilitation activity. Patients may be able to lead more active and productive lives if other rehabilitation interventions such as physical, occupational, and recreational therapy, counseling, and education are made available to them on a regular basis. Joint goal-setting by informed patients and the facility staff assists this process. We believe the interdisciplinary team should refer patients to appropriate agencies and health professionals for additional services that the facility cannot provide.

This proposed rule does not incorporate the use of any particular measure of rehabilitation status because we do not believe there is consensus in the renal community about a specific measurement at this time.

g. Social Services

We would like to specify social service outcomes that must be included in the patient plan of care. However, we believe the social worker should identify social service outcomes based on the patient assessment (described at § 494.80(a)) as part of the plan of care goals for each patient.

Complex emotional and social factors affect the dialysis patient, including, but not limited to, changes in self-image, loss of independence, changes in financial security, loss of physical integrity, problems with sexual functioning, changes in roles, and coping with the anxiety and discomfort associated with treatment. We believe that the interdisciplinary team could influence many of these factors. We are soliciting comment regarding the most effective way to address these factors within a patient plan of care requirement that supports an effective level of emotional and social well-being for the patient.

Work is being done on a variety of assessment instruments that could measure the emotional and social well-being of patients. We considered the current experiences with such instruments as the Kidney Dialysis Quality of Life instrument, the RAND Short Form-36, and the Duke Health Profile ((Hays, pp. 329–338); (Rand Corporation, (1997)); and (Parkerson, pp. 1056–1069), respectively). However, at this time we do not believe that there

is a consensus on a single instrument or a level of psychosocial achievement for dialysis patients that could be included as a specific measure for a patient plan of care requirement.

As specified in existing § 405.2163(c), the social worker is responsible for counseling the patient and the patient's family, assisting the patient with the emotional adjustment to ESRD and dialysis treatment, performing crisis intervention, coordinating referrals and other community services, and arranging other benefits. Social workers can, in some instances, provide some of the necessary care and services for the patient to achieve and sustain an effective level of emotional and social well-being. For example, a necessary care and services component of social services is facility staff counseling and educating the patient and providing necessary information for the patient to have a smooth transition to life on dialysis. The social worker has an important role in addressing patient behavior that may be challenging or disruptive. The social worker is uniquely qualified to provide counseling, anger management, and emotional support services to patients with ESRD. In cases in which the social worker is not able to provide the necessary services for the patient to adapt to dialysis treatment, the social worker should refer patients to appropriate agencies and health professionals for additional services. We are soliciting comments regarding the potential for an outcome-based requirement for social services in the patient plan of care.

2. Implementation of the Patient Plan of Care (Proposed § 494.90(b))

The patient plan of care stems from the patient comprehensive assessment that identifies patient care needs. Proposed § 494.90(b)(1) would require that the patient's plan of care be completed by the interdisciplinary team, signed by the patient or the patient's designee, and implementation must begin within 10 calendar days after an assessment is completed. As stated in the patient assessment condition, the facility interdisciplinary team has 20 days from the initiation of dialysis treatment to complete the comprehensive assessment. After the assessment has been completed, the interdisciplinary team has 10 days to develop the patient's plan of care. This gives the dialysis facility a maximum of 30 days to complete the comprehensive assessment and the patient plan of care. We selected 10 days for completion of the patient care plan because the plan directs the patient's treatment, and therefore, the plan of care should be initiated as soon as possible. Clearly, we are limiting a facility's flexibility when we identify a timeframe for development of the plan of care. However, we believe that a timely, accurate, comprehensive plan of care is critical for planning patient care and achieving desired health care outcomes. We believe that a maximum of 30 days to complete the assessment and patient plan of care is ample time, considering the seriousness of the condition that necessitates the dialysis. We are soliciting comments on both the appropriateness of prescribing a timeframe as well as the suitability of the proposed timeframe.

We propose at § 494.80(d) that patients be reassessed as needed but no less frequently than annually. The patient plan of care would also be reviewed at least annually since we are proposing that every comprehensive assessment must be followed by completion and implementation of the plan of care. Existing § 405.2137(b)(4) states that care planning is conducted monthly for unstable patients and every 6 months for those patients who have become stabilized. While we have retained patient plan of care monthly timeframes for unstable patients (proposed at § 494.80(d)(2)), we believe that the 6-month review requirement for stable patients may be unnecessarily burdensome.

The individualized patient plan of care is not static and will require adjustments as the needs of the patient change, particularly if the patient is not stable. We propose at § 494.90(b)(3) that the interdisciplinary team must adjust the patient plan of care to achieve and sustain the specified patient outcomes goals. New strategies may need to be implemented as assessment, response, and patient preference information requires. If the targeted plan of care goal is achievable but is not being attained, the facility must implement an improvement plan to reach the goal.

We recognize that patient outcomes are determined in part by factors outside of the dialysis facility's control, such as demographics, the systemic effects of the underlying renal disease, and patient preferences and compliance. Further, we recognize that health care delivery is dynamic and that all patients may not be achieving for example, the expected delivered dose of dialysis at any specific point in time. If the patient is unable to achieve the desired health outcomes, the plan of care should be adjusted to reflect the patient's condition along with an explanation, and any opportunities for improvement in the patient's health should be identified. The explanation for not achieving the specific level of care may include patient preferences and patient noncompliance.

Proposed § 494.90(b)(4) would specify that the facility must ensure every patient is seen at least monthly by a physician providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician or communicated from the physician's office and placed in the beneficiary's medical record. We are proposing this requirement based on a continuing concern of beneficiaries regarding the amount of interaction between patients and their physicians. We chose the time period of at least once a month because physicians have traditionally been paid for their services to renal patients on a monthly basis through the monthly capitation payment. Patients who are not stable will need to see the physician more frequently than our proposed minimal timeframe. According to preliminary information from the Dialysis Outcomes and Practice Patterns Study (DOPPS), better patient outcomes are associated with high levels of patient contact from the physician. Almost 70 percent of the dialysis patients sampled in the United States, as part of the DOPPS, see their physician once per week or more frequently, as reported by the nurse. However, we are concerned about the suggestion that as many as 5 percent of the dialysis patients may see their physician less often than once a month. While we are proposing a minimum monthly physician visit (without specifying any duration for the visit itself), we do not want to discourage more frequent visits. On November 7, 2003, we published a final rule (68 FR 63196, 63216) regarding the revisions to the payment policies under the physician fee schedule for calendar year 2004. This rule aligns payment incentives with the frequency of the physician's evaluation of the dialysis patient. In addition, the rule assigned new G codes that associate a higher payment to a physician who provides more visits within each month to an ESRD patient. Physicians should see patients and monitor their care as often as is medically necessary to ensure that they are progressing towards the specified outcomes.

We believe it is important for physicians to see in-center hemodialysis patients periodically while they are undergoing dialysis in order to monitor the quality of care they are receiving and to address the patient's particular clinical concerns and needs while in the treatment environment. We believe

periodic in-center monitoring by the patient's hemodialysis physician is an accepted medical practice and would not impose any additional burden on dialysis facilities. We are soliciting comments regarding whether physicians should be required to see their in-center patients periodically while those patients are being dialyzed in the dialysis facility. Such in-center visits would not be in addition to the monthly requirement proposed in § 494.90(b)(4).

3. Transplantation Referral Tracking (Proposed § 494.90(c))

We are proposing at § 494.90(c) that the interdisciplinary team track the results of each kidney transplant center referral and monitor the status of any facility patients who are on the transplant wait list. The routine exchange of information between the dialysis facility and the transplant center is important so that both facilities know who is active on the transplant wait list, who is temporarily or permanently inactive, and who is under evaluation. In addition, there may be a need to coordinate histocompatibility testing, which must be completed on a monthly basis. We invite comment on the coordination of the transplant process and the method and frequency of communication with the transplantation center.

4. Patient Education and Training (Proposed § 494.90(d))

The existing regulations do not specifically address patient education and training for in-center patients. However, in § 494.90(d), we are proposing to stipulate that the patient plan of care must include, as applicable, education and training for patients and families in all relevant aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and education regarding renal transplantation. When kidneys fail, the resulting physical changes stimulate a chain of psychological and physiological events that alter the lives of the affected individuals and their families. The education of patients and their families goes beyond providing the necessary information for patients to make an informed choice regarding treatment modality. Because the life changes associated with beginning dialysis are so profound, patients and their families need to be educated and trained about strategies for successful adaptation to dialysis, optimizing functional status, employment options, and many other issues. Patients and their families must learn about the disease and the possibilities of life beyond it and then assume responsibility for their own health by complying with the treatment plan and participating actively in rehabilitation activities. Educating and training patients and their families is key to a successful transition to a life with dialysis.

However, not all elements of the existing § 405.2137 will be retained in proposed § 494.90. In accordance with our approach to consolidate all similar standards, we propose to move the requirements in existing § 405.2137(b)(5) regarding the transfer of the patient's medical records to the proposed medical records condition for coverage (§ 494.170), and move the requirements in existing § 405.2137(b)(6) regarding the monitoring of home dialysis patients to the proposed Care at Home condition for coverage (§ 494.100). We believe that this reclassification will improve the proposed regulation's organization.

D. Condition: Care at Home (Proposed § 494.100)

[If you choose to comment on issues in this section please include the caption ''Care at Home'' at the beginning of your comments.]

1. Dialysis of the ESRD Patient in the Home Setting

Home dialysis has been shown to have a positive effect on a patient's quality of life. Home dialysis affords the patient control over the scheduling and setting; it can be done in comfortable, familiar surroundings; and it is less disruptive to family life and employment than in-center dialysis.

The existing requirements for home dialysis are located in four sections: (1) Definitions (§ 405.2102); (2) patient care plan (§ 405.2137(b)); (3) medical records (§ 405.2139); and (4) minimal service requirements (§ 405.2163(e) and (g)).

Existing § 405.2102 defines home dialysis as dialysis performed by an appropriately trained patient at home.

Existing § 405.2137(b) states that home dialysis patients will receive a written care plan with the same criteria that are specified for in-center patients. Section 405.2137(b)(6) requires the ESRD facility to conduct periodic monitoring of the patient's home adaptation, including visits to the home by ''qualified facility personnel'' as appropriate. Section 405.2137(b)(7) contains patient care plan requirements that apply to home dialysis patients who use erythropoietin, including: (1) Monitoring diet and fluid intake; (2) medication usage; (3) hematocrit and iron stores; (4) reevaluations of the dialysis prescription; (5) a method for physician follow-up on blood tests and a mechanism to inform the physician of the results; (6) training the patient to identify signs of hypotension and hypertension; and (7) decreasing or discontinuing erythropoietin usage if hypertension is uncontrolled.

Existing § 405.2139 requires facility to maintain ''complete medical records'' on all patients, including its home patients. Section 405.2139(d) contains requirements regarding medical records information generated by self-dialysis patients and entries of medical records information by trained self-dialysis patients, or ''trained assistants,'' countersigned by facility staff.

Existing §§ 405.2163(e)(1) through (6) list a facility's home dialysis support services including: (1) Surveillance of the patient's home, including periodic visits; (2) consultation for the patient with a qualified social worker and qualified dietitian; (3) a record keeping system that assures continuity of care; (4) installation and maintenance of equipment; (5) testing and appropriate treatment of the water; and (6) ordering supplies on an ongoing basis.

Existing § 405.2163(g)(1) through (4) requires the facility or physician responsible to make a comprehensive patient assessment that includes the following: (1) Preselection monitoring, including the patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure; (2) conditions the patient must meet, including a hematocrit (or comparable hemoglobin) hematocrit level of 30 percent (for patients initiating erythropoietin treatment), or a level of 30 to 33 percent (for patients already under the care of a dialysis facility or physician); (3) a requirement that patients or caregivers must be trained to inject erythropoietin, read and understand drug labeling, and observe aseptic techniques; and (4) the assessment must find that erythropoietin can be refrigerated in the patient's residence and potential risks and hazards related to the drug and syringes are understood by the patient.

In § 494.100, we proposed requirements that are only applicable to home dialysis. Since not every facility chooses to provide home dialysis, this condition would apply only to a facility that provides these services.

We propose in the opening paragraph of § 494.100 to retain the implicit requirement in existing § 405.2163 that services to home patients are at least equivalent to those provided to in-center patients. Home dialysis patients are patients of the ESRD facility; and therefore, they are entitled to the same rights, services, and efforts to achieve

expected patient outcomes as any other patient of the facility.

We are proposing to address home dialysis training in § 494.100(a). In our deliberations regarding home dialysis training requirements, we took into account the considerable lifestyle changes associated with initiating home dialysis and the unique needs of patients and caregivers engaged in home dialysis. Patients and their caregivers need to be trained and educated about strategies for successfully adapting to dialysis at home, ways to optimize functional status, proper self-dialysis procedures, and many other issues. Therefore, the processes of educating and training patients and their caregivers are crucial to a successful transition to a life with dialysis and to achieving good patient care outcomes.

In the opening paragraph of § 494.100(a), we are proposing that before the initiation of home dialysis, when the caregiver changes, or when the home modality changes, that the facility's interdisciplinary team is responsible for providing self-dialysis training to the home patient, the patient's designated caregiver, or both. Self-dialysis (as defined in existing § 405.2102(b)(2)(ii) and proposed § 494.10) means dialysis performed with little or no professional assistance by an ESRD patient who has completed an appropriate course of training. Home dialysis training may be only be provided by a dialysis facility certified to provide home dialysis services. Durable medical equipment (DME) companies cannot provide home dialysis training. We are proposing in § 494.100(a)(1) to modify the existing requirement at § 405.2102(d)(3) that self-dialysis training must be conducted by a registered nurse with 18 months of clinical experience and at least 3 months of specialized experience in training dialysis patients in self-care. We are proposing to modify these requirements to state that self-care training must be conducted by a registered nurse who meets the personnel qualifications specified in § 494.140(b)(2) (that is, 12 months clinical experience and an additional 3 months of clinical experience in the specific modality for which the registered nurse will provide training). As previously stated, home dialysis training is crucial to achieving desired patient outcomes; and therefore, we believe the initial training a patient receives must be provided by an experienced health care professional.

Existing § 405.2102 requires that a facility provide a training program for self-dialysis and home dialysis patients, if it chooses to provide this service, but it does not specify the content of that training program. Therefore, we are proposing the following subject areas for home dialysis training programs in §§ 494.100(a)(3)(i) through (a)(3)(x). These types of programs would, at a minimum, be required to provide training in the following:

- The nature and management of ESRD.
- The full range of techniques associated with the applicable type of home dialysis, including effective use of dialysis supplies and equipment in achieving the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve a hematocrit level of at least 33 percent or a hemoglobin level of 11 gm/dl.
- Nutritional care planning.
- Achieving and maintaining emotional and social well-being.
- How to detect, report, and manage potential complications.
- Availability of support services and how to access and use available support services.
- How to self-monitor health status and record and report health status information.
- How to handle medical and non-medical emergencies.
- Infection control precautions.
- Proper waste storage and disposal procedures.

While we recognize that specifying the topics for a training program appears to be inconsistent with our goal of reducing process-oriented requirements, we believe it is critical and necessary that the items listed above be required, so that patients and caregivers are fully informed regarding the health and safety procedures that must be followed and precautions that must be taken when providing dialysis at home.

Home patients are not seen 3 times a week by facility staff like in-center patients; and therefore, the quality and content of home training given to patients and their caregivers is an extension of the care and monitoring that would normally be provided in the dialysis facility. In addition, the facility is responsible for ensuring that home dialysis patients are achieving the desired outcomes, and this training will inform home care patients or their caregivers or both of the plan of care that must be followed (see proposed § 494.90) to achieve the expected results.

We propose in §§ 494.100(b)(1) through (3) that the dialysis facility: (1) Record who received the training described in § 494.100(a)(3) and indicate that the patient or caregiver demonstrated adequate comprehension; (2) retrieve and review self-monitoring data from patients or caregivers at least every 2 months; and (3) maintain this information in the patient's medical record. The goal of the proposed standards is that facilities effectively coordinate the care of all patients, including home dialysis patients, to achieve the desired outcomes. As previously stated, we recognize that home patients do not see facility staff as frequently as in-facility patients, so the purpose of this proposed requirement is to ensure that the facility's interdisciplinary team periodically monitors the care of home dialysis patients' plans of care.

Existing § 405.2139(d) requires dialysis facilities to collect medical information generated by self-dialysis patients, but it does not specify the frequency of the data collection. By proposing at § 494.100(b)(2) that the home patient's facility collect and review information at least every 2 months, we ensure the interdisciplinary team can determine if the patient is having problems with any aspect of the dialysis therapy at regular intervals. We would recommend that the facility collect data that will enable it to determine if home patients are adhering to the plan of care and achieving expected outcomes. Based on the data received, the facility staff can determine if the patient or caregiver needs to be retrained or, in some cases, determine that the patient is no longer a suitable candidate for self-care dialysis. As with in-facility patients, the goal of collecting data on home dialysis patients is to ensure that they are achieving the expected outcomes.

We propose to retain many of the existing support services requirements at § 405.2163(e) in proposed § 494.100(c). We have always taken the view that the law and the regulations require that the facility provide all of these support services, regardless of whether the dialysis supplies are provided by the dialysis facility or a durable medical equipment (DME) company, to the extent that they are medically necessary for a beneficiary's care. In addition to meeting other requirements, the proposed Care at Home condition is intended to assure that home dialysis patients, including those residing in nursing facilities (NFs) or skilled nursing facilities (SNFs), are receiving care that is comparable to the care provided to in-facility patients. Thus, the support services provided to home dialysis patients should parallel the treatment provided to patients in a dialysis facility.

We are proposing in § 494.100(c)(1)(i) to retain the existing requirements at

§ 405.2137(b)(6) regarding periodic surveillance of the patient's home adaptation, including provisions for visits to the home by facility personnel.

In addition, we are proposing in §§ 494.100(c)(1)(ii) through (iv) to retain existing requirements in §§ 405.2137(b) and 405.2163(e) to: (1) Coordinate the home patient's care by a member of the facility interdisciplinary team; (2) develop and periodically review the patient's plan of care (see § 494.90) to address the patient's needs and achieve expected outcomes of care; and (3) consult with the members of the interdisciplinary team as needed.

Existing § 405.2163(e)(2) requires consultation with a qualified social worker and dietitian. We are proposing in § 494.100(c)(1)(iv) to strengthen this requirement by including any member of the patient's interdisciplinary team because some home dialysis patients may experience problems or have needs that require consultation with several members of the interdisciplinary team, and we do not want to limit their access to appropriate care. In addition, we recognize that patients who are new to dialysis therapy need a period to adjust and adapt to their treatment. Initially patients may experience anxiety while learning self-care skills, how to perform the dialysis treatment, how to modify their diet, and how to change their behavior.

We also believe the interdisciplinary team must be responsible for the development and periodic review of the patient's individualized, comprehensive care plan based on the comprehensive assessment (*see* § 494.80) that specifies the services necessary to address the patient's needs and includes measurable and expected outcomes. We are proposing in § 494.100(c)(1)(iii) to expand the existing requirements by including a statement that the patient's comprehensive plan of care will be developed and reviewed by the interdisciplinary team to address the patient's needs and to achieve the expected outcomes of care. To that end we are encouraging and recommending that dialysis facilities adopt the same clinical performance measures for home patients as those that are used for in-center patients. As previously stated in the discussion of the patient plan of care condition for coverage (§ 494.90), the goal is to obtain input from each member of the interdisciplinary team as well as from the home patient so as to develop a comprehensive plan of care that indicates the services necessary to address the home patient's needs. The home dialysis patient's plan of care should stipulate the services that are to be furnished to achieve and maintain the expected outcomes of care.

We are proposing in § 494.100(c)(1)(v) to retain and expand the existing requirement at § 405.2163(e)(5) to monitor the quality of the water used by home hemodialysis patients. We are specifically including onsite evaluation of the water system. Since we have incorporated by reference the AAMI standards regarding water quality at § 494.40(a)(1)(i) and (ii), we are also proposing that a facility adhere to the applicable AAMI guidelines in determining whether the home dialysis patient's water system meets acceptable standards. If water supplies are biologically or chemically contaminated, contaminants may be passed to the patient during the dialysis session, leading to infection or other adverse consequences. Therefore, a dialysis facility must monitor the quality of water used in treatments, as well as monitor the equipment used in water treatment. Because water is one of the most important aspects of health and safety, we are proposing in § 494.100(c)(l)(v) to require that the facility conduct onsite evaluation of the patient's water system if the AAMI-specified analysis of the water quality indicates contamination or if the home patient demonstrates clinical symptoms associated with water contamination. The dialysis facility must ensure that any problems with the water treatment system are corrected. If the problem cannot be corrected immediately, the dialysis facility must arrange for backup dialysis until the water quality at the patient's home can be adequately restored.

We are proposing in § 494.100(c)(1)(vi) to retain the existing requirements of section 1881(b)(9) of the Act and §§ 405.2163(e)(4) and (e)(6) of the regulations that require the facility to install and maintain medically necessary home dialysis supplies and equipment prescribed by the attending physician. In addition, for those home patients not receiving equipment and supplies from a DME company the dialysis facility must also purchase and deliver the necessary home dialysis supplies and equipment.

Furthermore, we propose in § 494.100(c)(1)(vii) to require the facility to plan for and arrange for emergency backup dialysis services. This plan should address how emergency situations will be dealt with, and should hemodialysis be required, include a plan for obtaining this service.

We are proposing in § 494.100(c)(2) to retain the requirement at § 405.2163(e)(3) that a facility maintain a record keeping system that promotes continuity of care. The medical record is used for diagnosing, treating, and caring for the patient. We believe this requirement is vital to the effective coordination of services provided to home dialysis patients because the medical record indicates what care has actually been provided and what outcomes have been achieved. The medical record documents the services provided by the interdisciplinary team members and provides an accurate picture of the patient's progress in achieving care goals. Further, it provides the data for evaluation and documentation of the quality and appropriateness of care delivered. Adequate record keeping is vital to ensure continuity of care and to ensure that the home dialysis patient is receiving quality care.

In addition, the patient's supplier is often not part of the facility staff; and therefore, it may be difficult to ascertain the services they provide the home patient. In some instances, the services of home patients are not effectively coordinated. As a result, the facility staff is often not able to provide comprehensive care to home patients, and the quality of care suffers. In an effort to encourage facilities to coordinate services effectively, § 414.330(a)(2)(ii)(C) would require that the patient's supplier report to the facility, every 30 days, all services and items furnished to the beneficiary so that the information can be documented in the patient's medical record. One of our primary goals is to have the care of home patients parallel the care of in-facility patients, and this can only be accomplished if all information on patient care is reported to the facility. We selected 30 days because monthly reporting and billing is commonly used by dialysis facilities and by suppliers and we believe that this will not produce additional burden. All patient data are necessary to effectively evaluate the patient's dialysis prescription and make changes to the patient plan of care. A less frequent reporting timeframe would compromise efforts to correct deficiencies in the patient's plan of care (for example, adjustments to the dialysis prescription) by the patient's physician and other necessary corrective actions by the patient's interdisciplinary team. We welcome comments on the proposed timeframe for the patient's supplier to report to the facility.

2. Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities

The existing regulations allow hemodialysis to be provided within NFs and SNFs when there is a certified

hemodialysis facility on-site or adjoining the NF or SNF and when the patient is a home dialysis patient who has been appropriately trained. In a March 19, 2004 letter to State survey agency directors entitled, ''Clarification of Certification Requirements and Coordination of Care for Residents of Long-term (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services'' (Reference: S&C–04–24), we clarified certification requirements and coordination of care expectations for residents of LTCs who receive dialysis. On July 8, 2004, we sent State survey agency directors and addendum to the March 19, 2004 letter that included as an attachment follow-up questions and answers regarding the scope of the guidance and the responsibilities of the providers (Reference: S&C–04–37). In this proposed rule, we are soliciting comments on a wide range of issues affecting the population of patients who are nursing home residents and who desire to be dialyzed in the nursing home. We have received inquiries as to whether an institutionalized setting such as a long-term care facility may be considered to be a beneficiary's ''home'' for self-dialysis purposes. In the past we have provided guidance in response to these inquiries. Home dialysis is currently only an option for NF or SNF patients when certain conditions are satisfied: (1) The NF or SNF must be considered to be the patient's home (for short NF or SNF stays, such as rehabilitation or brief recovery time admissions, the nursing home would not be considered the patient's home since the expectation is that the patient would soon be discharged and return to their own home); (2) the patient (and his or her family member or caregiver) must complete the home dialysis training; (3) all home dialysis patients must have their own dialysis machine, equipment, and supplies; and (4) home dialysis patients must receive their support services from a certified dialysis facility.

Currently the NF or SNF patient who requires hemodialysis may be transported to a certified outpatient hemodialysis facility or may receive treatment from a certified hemodialysis facility available within or adjoining the NF or SNF. We recognize the hardship placed on long-term care patients who must be transported to offsite dialysis facilities 3 times per week. Since there is potential growth for home dialysis in NFs and SNFs because of changing demographics in both the ESRD population and the general population, it may be appropriate for us to provide further guidance regarding the regulatory expectations for the provision of dialysis in the NF or SNF.

Dialyzing patients in NFs or SNFs without a certified ESRD facility within or adjoining the NF or SNF may present both opportunities and risks. Dialysis patients who remain in the NF or SNF are less likely to miss medication administration, treatment regimens, meals or planned activities during time that would otherwise be spent in waiting and transportation to and from a dialysis facility. We know that some patients would prefer to stay in their residence and dialyze while others would prefer to be transported to a certified dialysis facility for care. We believe that both choices should be available for NF or SNF residents, and we believe that both choices should provide patient protections for health and safety. In addition, we believe that patients receiving dialysis in a NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility. Finally, we need to assure that, in providing hemodialysis treatments in a NF or SNF, the care of other residents in the NF or SNF not requiring dialysis is not negatively impacted. We are soliciting comments on whether the current home dialysis regulations need to be modified to protect this vulnerable population, and if so, in what ways and under what particular set of circumstances.

In the current ESRD regulations, the home dialysis training requirement presents a significant barrier in providing home dialysis to NF or SNF residents as the patient may be untrainable and may not have a ready caregiver who could be co-trained to assist the resident in performing dialysis. The patient's role in home dialysis is defined at § 405.2102 under the definitions section of the requirements. The regulations require the patient to take part in the training. We have received correspondence requesting that the home-dialysis training requirement be waived for NF or SNF residents. It has been our long-standing policy to encourage home dialysis. We are also aware of the current limitations relative to severely debilitated patients who are ineligible for home dialysis based on the training requirement. Given the relative acuity of nursing home patients, there are safety concerns associated with allowing patients in nursing homes to be home dialysis patients. These patients may be less able to voice symptoms/problems then the typical ESRD home patient. In addition, the dialysis care of a patient who requires nursing home services may be more complex than the dialysis care of an independent home dialysis patient, and given their frailty, these patients may be more vulnerable than an independent home dialysis patient. Because of this, we have significant safety concerns about encouraging home dialysis, provided by multiple caregivers, who may not have any dialysis experience, in this setting.

Home dialysis patients may choose to obtain their dialysis supplies and equipment from either the dialysis facility that provides the home training and support services (Method I payment) or from a DME company (Method II payment). The dialysis facility may have more patient contact and be more able to determine that necessary supplies are provided at the right time and in the right amounts to meet the needs of home patients due to the enhanced patient contact. If hemodialysis were provided to NF or SNF residents within the home dialysis model, these patients would continue to be able to choose between Method I and Method II.

In order to address the issue of home dialysis in the NF or SNF, we believe there needs to be clarity about the various roles and responsibilities of the certified ESRD facility providing dialysis care and the responsibilities of the NF or SNF when there is no certified ESRD facility onsite or adjoining the NF or SNF. While we have addressed many of these concerns relative to the existing regulations through guidance to the State survey agency directors, the important issues that we would have to address through new rulemaking and the issues on which we request comment are discussed below.

a. Delineation of Responsibility

We believe the home hemodialysis services provided in a NF or SNF should be provided under the direction of a certified dialysis facility that is responsible for the dialysis care provided to the ESRD patients, for assuring that the NF or SNF is capable of providing appropriate pre- and post-dialysis care, and for assuring that there is coordination of care between the two entities, that is, the nursing home and the ESRD facility. In order to assure that roles and responsibilities are clearly delineated prior to the initiation of care, we believe there should be a written agreement (specifying responsibilities and the coordination of care) between all parties providing the care, including the NF or SNF (and the DME supplier, if applicable).

b. Applicable ESRD Conditions for Coverage

Consideration must be given as to whether home dialysis care provided in a NF or SNF must comply with all of the proposed conditions for coverage, except § 494.120, that governs special purpose dialysis facilities and the specification at § 494.180(d) that services must be provided on or contiguous with the premises.

c. Nursing Coverage

The existing regulations (§ 405.2162(b)) require that a licensed health professional (for example, physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care whenever patients are being dialyzed. This proposed rule would require (proposed § 494.180(b)(2)) that a registered nurse be on the premises whenever in-center patients are being treated. We believe that there would be a comparable risk to patient health and safety if a licensed nurse was not on the premises of the NF or SNF and available during multiple simultaneous home NF or SNF dialysis treatments. Consideration must be given as to whether this registered nurse could be a NF or SNF registered nurse trained by the ESRD facility, or a registered nurse provided by the ESRD facility to be available during NF or SNF hemodialysis treatments.

If the NF or SNF were allowed to provide this registered nurse to be available during hemodialysis treatments then the implications for care (requiring registered nurse attention) provided to other NF or SNF residents must be considered. We are considering whether a limitation of the NF or SNF registered nurse's duties is necessary, so that the nurse is available to meet dialysis needs while another nurse tends to the NF or SNF residents (for example, such as the absence of direct NF or SNF resident care responsibilities and allowance of only administrative duties). When considering whether the NF or SNF registered nurse may be the licensed individual responsible for overseeing resident care when residents are being dialyzed, the provision of training by the ESRD facility for this individual also must be addressed.

While the registered nurse would oversee the dialysis, a trained caregiver would administer the dialysis treatment. In a typical home dialysis patient situation, the ratio of patient to caregiver is one-to-one. We solicit comments on whether we should address patient to caregiver ratios in a situation when the NF or SNF is considered the patient's residence.

d. Training

We believe that training provided by the certified ESRD facility should be specified and the ESRD facility should be responsible for providing training to NF or SNF staff and to all caregivers who will be working with the ESRD patients. These caregivers could possibly include the nursing and support staff of the residential institution, dialysis facility nurses and patient care technicians, and the caretaker that may be provided by the DME supplier, if available and the patient is a Method II home dialysis patient. We note that Medicare does not provide additional reimbursement for caregiver services within the current payment system. We believe that caregiver-training requirements that are similar to the training specifications for home dialysis patients may be appropriate.

e. Monitoring

If we were to propose requirements on this topic, we believe that the certified ESRD facility should be responsible for monitoring the care of the ESRD patient in the NF or SNF. We also believe that the dialysis facility should assure that trained caregivers be present in the room with the patient at all times while the hemodialysis is being provided. This ensures that a knowledgeable individual is available to assist the patient if any problems arise.

We believe that the ESRD facility should—(1) periodically assess the ability of the staff (NF or SNF staff and caregiver) responsible for care of the ESRD patient to assure that they are competent in their tasks; (2) retrieve and review complete data, including laboratory data, clinical data, outcome data, and interdisciplinary team notes to assure that adequate care is being provided; (3) monitor the care of the patients, using appropriate clinical standards; and (4) work with the NF or SNF staff to monitor whether dialysis treatments being provided in the nursing home negatively impact the care of other NF or SNF residents and correct such impact as appropriate.

We believe that the dialysis facility should ensure that care being provided to patients receiving dialysis in a NF or SNF is comparable to the care provided to facility patients. Thus, the support services provided to NF or SNF residents should parallel the treatment provided to patients in a dialysis facility. Therefore, we believe that the dialysis facility providing dialysis in a NF or SNF must also: (1) Provide periodic monitoring of the institutional residence to assure that appropriate care is being provided; (2) provide monitoring of supplies and equipment; (3) maintain medical records in both the NF or SNF and at the certified ESRD facility; and (4) assure that patient rights are protected as they would be in a dialysis facility, including access to a formal grievance process by the patient or the patient's guardian or advocate.

We want to ensure that the health and safety of NF or SNF hemodialysis patients is protected and so we are soliciting comment on the provision of hemodialysis in the NF or SNF on the issues discussed above. Specifically, we solicit comment on what competency requirements and experience/qualifications should be proposed for the caregiver (who is not a patient's family member) and for the registered nurse, what restrictions should be placed on the caregiver or the registered nurse or both, and whether caregiver to patient ratio limits should be proposed. We are interested in any suggestions regarding this issue to provide for the specific needs of this vulnerable population, and on how we can make these requirements more flexible to meet the needs of the providers, while providing appropriate patient protections.

E. Condition: Quality Assessment and Performance Improvement (Proposed § 494.110)

[If you choose to comment on issues in this section please include the caption ''QAPI'' at the beginning of your comment.]

An integral part of our effort to move toward a patient outcome-based system is the facility level quality assessment and performance improvement (QAPI) program. We propose to require that a dialysis facility create its own tailored program for quality improvement based on the framework provided in this condition. Existing §§ 405.2112(c) and 405.2113(a) address quality standards for patient care in the context of the ESRD network organization's role. Although § 405.2134 requires each dialysis facility to participate in network activities and to pursue network goals, there is currently no clear Federal requirement for an ongoing facility-specific, patient-centered continuous quality improvement program. The focus on outcomes in this proposed rule is a result of the fundamental shift in approach to performance expectations within the health care industry and efforts within the renal community to define and examine outcomes.

In 2000, the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) conducted an extensive review to ascertain the effectiveness of our monitoring of the ESRD program. Their subsequent report was entitled ''External Quality Review of Dialysis Facilities: A Call for Greater Accountability'' (DHHS/OIG, June 2000). The purpose of this review was to ''assess external mechanisms HCFA relies upon to monitor the quality of care provided by dialysis facilities to Medicare beneficiaries with ESRD.'' This OIG report provides a thorough review of the external quality oversight of dialysis facilities in the United States and the roles played by CMS, the State survey agencies, and the ESRD networks. The OIG recommended that dialysis facilities be required to conduct their own quality improvement programs. The OIG also recommended that facilities be required to establish internal systems for identifying and analyzing the causes of medical injuries and medical errors. Another recommendation was to require facilities to monitor patient satisfaction. The Institute of Medicine's (IOM) 1991 report, ''Report on Kidney Failure and the Federal Government'' suggests that relating the conditions for coverage to patient outcomes would assist the quality assurance efforts of the ESRD program (IOM, 1991).

The 2001 IOM report, ''Crossing the Quality Chasm: A New Health System for the 21st Century'' addresses the need to narrow the quality chasm between the potential benefits of medical science and technology and the actual level of health care provided in the United States (IOM, 2001). The report offers a strategy and action plan for building a stronger health system over the coming decade. The report presents multiple challenges to health care leaders and points out that all organizations can improve their performance by incorporating care process and outcome measures into their daily work. In addition, many renal groups (including the RPA, the American Nephrology Nurses Association, the NKF, and the American Association of Kidney Patients) have developed similar positions. We believe that the quality improvement activities in this proposed rule and the data systems of the future will provide an opportunity to focus more closely on patient outcomes. We believe that it is critically important that dialysis facilities examine the adequacy of their information technology and identify opportunities to improve and expand the use of such technologies to prevent medical errors and improve the quality of care. This Administration is committed to working with other public and private stakeholders to develop means for improving and expanding the use of information technologies (such as bar coding and computerized physician order entry systems) in health care settings.

Proposed § 494.110 would require that a facility develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program that reflects the complexity of the dialysis facility's patient population and its processes of care. The dialysis facility must take actions that result in performance improvements in the quality of patient care. We believe that dialysis facilities need to have a continuous quality improvement system in place to continually assess and improve health care delivery. The facility's quality improvement program should monitor the systems and processes of care that are used to achieve the targeted patient outcomes. This approach calls for facilities to systematically collect and analyze clinical data about the components of their care processes. The majority of facilities already collect clinical performance measures as described in the 2002 OIG report, which describes the quality improvement programs of large dialysis corporations (DHHS/OIG, January 2002). The 5 largest dialysis corporations (representing 67 percent of the total number of dialysis facilities) routinely collect data on at least 14 clinical performance measures; and therefore, requiring collection of those clinical performance data would not impose an additional data collection burden on most dialysis facilities. These types of data can be used to assess facility care processes and to identify opportunities for improvement. Once the opportunity has been identified, the facility should develop and implement an intervention strategy that focuses on the processes that need improvement, and then evaluate whether the improvement strategy achieved the desired results. The facility should reexamine goals that have been achieved and, if applicable, undertake new interventions to further increase the quality of care processes, outcomes, and patient satisfaction. The facility must continue to track its performance to assure that improvements in patient outcomes and patient satisfaction are sustained. This is what is meant by the cycle of continuous quality improvement.

This QAPI approach demands an evaluation of organizational performance and a patient-centered focus. The evaluation includes measuring actual performance, as well as the impact of the performance on patient outcomes and satisfaction. The evaluation answers the question: ''Did that process, treatment or procedure produce the targeted outcomes?'' The approach gives the facility the ability to analyze interdependent processes of care and adjust them to optimize the system for providing care.

1. Program Scope (§ 494.110(a))

We are proposing in § 494.110(a) to require that the dialysis facility's QAPI program address at least the following areas: (1) Adequacy of dialysis; (2) nutritional status; (3) anemia management; (4) vascular access; (5) medical injuries and medical errors identification; (6) hemodialyzer reuse program (if applicable); and (7) patient satisfaction and grievances. We believe that these areas are reflective of: (1) the degree to which the facility achieves desirable patient outcomes; the extent of patient safety within the facility; and (2) the level of satisfaction attained as the patient experiences the continuum of care.

Adequacy of dialysis has become an important clinical performance measure for benchmarking the quality of dialysis care. We believe that it is appropriate and necessary to consider using consensus performance measures in our health and safety standards for facilities. The NKF–K/DOQI guidelines for hemodialysis adequacy (guideline 4) provide minimal adequacy of hemodialysis levels of Kt/V of 1.2 and URR of 65, but do not suggest optimal dialysis target levels, based on their conclusion, after a literature review, that there is not sufficient data to make that determination (NKF, 2000).

The Hemodialysis Study sponsored by the National Institutes of Health began in 1995 and was a comprehensive randomized clinical trial of dose and flux interventions to identify improvements in therapy that will reduce hemodialysis mortality. The study entitled ''Effect of Dialysis Dose and Membrane Flux in Maintenance Hemodialysis,'' confirmed that the minimum dosage of thrice weekly hemodialysis as stated in the NKF–K/DOQI Guideline 4 (that is, Kt/V of 1.2 and URR of 65) is adequate and that, in general, a high dosage and special high-flux filters provide no added benefit in terms of survival, rate of hospitalization, and albumin levels to patients (Eknoyan, pp. 2010–2019). The Hemodialysis Study also found statistically nonsignificant data suggesting that higher dialysis dosage

appeared to reduce mortality and hospitalization for women in those who had been receiving hemodialysis longer than 3.5 years when they joined the study (DHHS/NIH, 2002).

A recent retrospective study suggests that the recommended minimal urea reduction ratio of 65 percent may be too low to provide for an optimal mortality benefit (Szczech, pages 738 through 745). Also, we recognize that there are several possible methods for calculating Kt/V. In addition, a major concern for accurate measurement of either URR or Kt/V is that small differences in the method and timing of the blood draw used for the postdialysis blood urea nitrogen (BUN) blood sample can make clinically important differences in the resulting hemodialysis adequacy estimates.

We acknowledge the need for consistency in the techniques used for blood withdrawal as well as the method or formula used to calculate the Kt/V value. We considered proposing requirements that specified pre and postdialysis blood draw methods and Kt/V calculation methods that might allow for more accurate benchmarking. However, we are not proposing a specific methodology at this time, because we believe it would be more appropriate to recommend and encourage dialysis facilities to adopt the methodology(ies) recommended by a consensus process such as the NKF–K/DOQI.

Despite these difficulties, dialysis facilities do use adequacy of dialysis as one of their benchmarks when evaluating the quality of peritoneal and hemodialysis patient care. The CMS ESRD CPM Project calculates the adequacy of dialysis measures for hemodialysis and peritoneal dialysis patients (that is, URR and Kt/V) that can be used by facilities and ESRD networks for benchmarking and comparison purposes. The CMS ''Dialysis Facility Compare'' website provides facility-specific adequacy-of-dialysis information in terms of what percentage of patients are receiving at least the minimal dose of dialysis (defined as a URR $\geq$ 65 percent). The use of minimal performance levels for adequate dialysis is widely used to allow for comparisons. However, facilities are encouraged to evaluate the needs of individual patients and to deliver the amount of dialysis that will promote optimal health outcomes for that patient.

In addition, we are proposing in § 494.110(a)(2)(ii) that the dialysis facility's QAPI program must also address nutrition. The nutritional status of the dialysis patient impacts the patient's morbidity, mortality, and overall quality of life. The nutritional status of the patient may be affected by medical symptoms, physiological responses to ESRD, the dialysis process itself, anemia, endocrine disorders, etc. The importance of nutritional status in dialysis patients is recognized in the K/DOQI clinical practice guidelines for nutrition of chronic renal failure and in the ESRD CPM Project's inclusion of serum albumin levels. Under the plan of care condition (proposed § 494.90) we are proposing that the serum albumin level be monitored on a monthly basis. The facility may track the serum albumin levels or any other pertinent markers of nutritional status as part of its QAPI program. The goal is to identify care system opportunities for improving patient nutritional outcomes and then develop and implement interventions that will potentially achieve the targeted outcomes.

We are also proposing in § 494.110(a)(2)(iii) that the QAPI program must include anemia management. Existing §§ 405.2137(b) and 405.2163(g) address the patient's hematocrit level as the indicator for the necessity for administering erythropoietin. In 1996, anemia was the subject of the first National Cooperative Project conducted by the ESRD networks. The reasons for selecting anemia both for the study and as an outcome measure included: (1) The prevalence of anemia among the Medicare population; (2) a consensus among the renal community that anemia is a major quality-of-life problem for dialysis patients and that proper drug manipulation can improve this condition; (3) the fact that commonly used measures of anemia (hematocrit and hemoglobin levels) are routinely collected by us when facilities bill Medicare for erythropoietin on the outpatient billing form; and (4) the relatively straightforward and easily accomplished process for monitoring hematocrit (or hemoglobin) levels.

The United States Renal Data System (USRDS) Annual Data Report and the ESRD CPM Project provides regional and national anemia data that allow for facility benchmarking. The NKF–K/DOQI clinical practice guidelines for Anemia of Chronic Kidney Disease (Guideline 4) recommend an evidence-based target for hemoglobin of 11–12 g/dL (and hematocrit of 33 to 36 percent) for erythropoietin therapy. In May 2000, according to the 2001 Atlas of ESRD in the United States (USRDS), 12 percent of prevalent dialysis patients (that is, patients who have received chronic renal replacement therapy for at least 90 days) with erythropoietin claims had hematocrits less then 30 percent and the risk of hospitalization is increased with hematocrit levels less than 30 percent. The 2001 ESRD Clinical Performance Measures (CPM) Project Annual Report revealed that 74 percent of in-center hemodialysis patients who were prescribed erythropoietin during the last 3 months of 2000 had a mean hemoglobin of equal to or greater than 11gm/dL (which is approximately equal to a hematocrit of 33 percent). This same report reveals that 63 percent of peritoneal dialysis patients prescribed Erythropoietin during the study period had a mean hemoglobin of equal to or greater than 11 gm/dL. This proposed rule uses anemia, as measured by the hematocrit or hemoglobin level, as an element of patient outcomes for both hemodialysis and peritoneal dialysis patients.

Vascular access insertions and complications (for example, infection) have received increasing attention over the past few years. The current ESRD network quality improvement project, Fistula First, is focused on vascular access. Complications associated with vascular access account for about 18.3 percent of ESRD patient hospitalizations (USRDS data from 2000) and is associated with high financial costs and diminished quality of life for the hemodialysis patient. Therefore, we are proposing in § 494.110(a)(2)(iv) that vascular access management be included in the facility's QAPI program. Facilities should look for opportunities to improve patient outcomes related to vascular access by reviewing ESRD Fistula First data and ESRD CPM Project data in conjunction with the NFK-K/DOQI clinical practice guidelines for vascular access. The ESRD CPM Project and the USRDS Annual Data Report provide regional and national data pertaining to vascular access. The NKF–K/DOQI clinical practice guidelines for vascular access provide valuable information useful to a facility QAPI program regarding vascular access management.

We are proposing in § 449.110(a)(2)(v) to require a patient safety component specific to medical injuries and medical errors identification as part of each facility's QAPI program. The IOM published a report entitled ''To Err is Human: Building a Safer Health System,'' that focused on the magnitude of medical errors, serious adverse events and the risks of medical care in the United States (IOM, 2000). Medical injuries and medical errors were also identified by the OIG as areas in which we should facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes. The OIG found

that medical injuries are not systematically monitored in dialysis facilities.

The Renal Physicians Association (RPA), in partnership with the Forum of ESRD networks and the Patient Safety Foundation, has formed a Patient Safety Committee to address patient safety in dialysis facilities. The Committee's report describes the work of 42 stakeholder representatives from 34 organizations as they engage in collaborative action planning (The Renal Physicians Association, 2001). The group identified challenges in improving patient safety, action options, and priorities. These participants have expressed their commitment to interorganizational collaboration on selected actions in the launch of the next phase of this initiative. The Phase I Report supports for the incorporation of patient safety activities into the conditions for coverage for ESRD, to encourage universal engagement in patient safety participation. This initiative provides resource information that may be useful to facilities as they develop their QAPI program to reduce medical errors and injuries.

We propose in § 494.110(a)(2)(vi) that if a dialysis facility reprocesses hemodialyzers they must include reuse systems in their QAPI program. The AAMI Reuse of hemodialyzers RD47 chapter (incorporated by reference in both the existing and the proposed conditions) includes guidelines for a reuse quality assurance program under section 14. Section 14 outlines quality assurance program areas that include: (1) Records that serve as the quality assurance foundation; (2) schedule of quality assurance activities; (3) patient considerations; (4) equipment; (5) physical plant; (6) supplies; (7) dialyzer labeling; and (8) reprocessing and preparation for dialysis. Since these activities are the same in the proposed conditions for coverage as in the existing conditions for coverage, there is no additional regulatory burden. Continuous quality management in the reuse area is important to ensuring patient safety.

Assessment of patient satisfaction was identified by the OIG as a means of identifying patient concerns often missed by the complaint process. The OIG recognized that patients play an increasingly important role in their own health care, and that techniques of assessing patient satisfaction have become increasingly sophisticated. We concurred with the OIG's recommendation. Therefore in § 494.110(a)(2)(vii), we are proposing that dialysis facilities include patient satisfaction in their QAPI programs. The OIG further recommended that we exert leadership to facilitate the development of a common instrument that facilities and others could use to assess patient satisfaction. Many facilities do currently use a patient survey as a means to assess patient satisfaction and some have experience in utilizing the results for quality improvement efforts.

We are proposing that facilities monitor patient satisfaction and grievances as part of the QAPI program and have the flexibility to use the method of their choice to meet this requirement. Tracking patient satisfaction and grievances allow the facility to identify any areas in which patients have expressed concerns. The facility can analyze this information and determine what aspect of facility operations needs improvement. CMS has an Intra-agency Agreement with AHRQ to develop a standardized patient experience of care instrument and survey protocol. In 2003, AHRQ conducted a feasibility study to assess the feasibility and applications (that is, quality improvement and public reporting) of a survey that measures dialysis patients' experience of care in renal dialysis facilities. In the August 25, 2003 **Federal Register** (68 FR 51017), AHRQ published a notice that identified and cataloged existing surveys and survey results made available to the team and presented the exhaustive literature review that was performed. In addition, a Technical Expert Panel consisting of ESRD patients and professionals was consulted. AHRQ's ESRD Consumer Assessment of Health Plan Survey (CAHPS) Feasibility Final Report and the CMS response can be found on *http://www.cms.hhs.gov/quality* (follow the ESRD link to the CAHPS link).

In the Feasibility Report, AHRQ recommended that a standardized survey for measuring in-center hemodialysis (ICH) patients' experience and ratings of their care be developed that could serve several important and distinct purposes. An ICH CAHPS survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that we can use for public reporting and monitoring purposes. The survey would be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.

In a January 30, 2004 **Federal Register** notice (69 FR 4520) published as part of the Paperwork Reduction Act (PRA) process, a draft survey and pilot test plan were issued. On July 23, 2004, a second **Federal Register** notice (69 FR 44012) was published and the package including the draft survey and pilot test plan was submitted to OMB at that time.

We will take into consideration the practical difficulties and potential burden on facilities that may result from requiring the use of a common instrument for assessing patients' experience of care. However, we invite comment on the value of utilizing one common survey that can yield information permitting comparisons of facilities across the nation.

We are also interested in how facilities will assess the effectiveness of their internal grievance adjudication process, track the outcomes of patient grievances, and identify meaningful criteria for evaluation and tracking purposes. We are soliciting comment on how evaluating and tracking grievances can be used to improve patient outcomes of care.

2. Monitoring Performance Improvement (Proposed 494.110(b))

We will specifically expect a facility whose treatment outcomes vary significantly from accepted standards to identify the reasons for poor outcomes and implement improvement projects to achieve expected outcomes. Therefore, we are proposing in § 494.110(b) that the dialysis facility must take actions that result in performance improvements and must track performance to assure standards are met and that improvements are sustained over time. This action stimulates the provider to continuously examine and improve performance. In addition, we are retaining the requirement in existing § 405.2134 that requires a dialysis facility to participate in ESRD network activities and pursue Network goals.

3. Prioritizing Improvement Activities (Proposed 494.110(c))

The principal focus of the facility's continuous quality improvement program should be to establish a strategy to prioritize improvements in facility services so that performance improvements lead to better outcomes of care and increased satisfaction for patients. To this end, the proposed § 494.110(c) requires the dialysis facility to set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes. The facility must immediately correct any identified problems that directly or potentially threaten the health and safety of patients. Under the continuous quality improvement system, facilities should be analyzing care processes that

determine how the facility's performance has affected—positively and negatively—patients, especially in terms of what the patient actually experiences. This proposed requirement emphasizes the need for the facility to focus on the areas of performance where problems have been specifically identified, especially in areas relating to outcomes of patient care. By prioritizing areas of improvement, facilities can: (1) Identify areas where outcomes indicate a need for improvement; (2) define measures to improve outcomes; (3) review implementation of improvement actions; and (4) determine the success of the actions implemented to improve the performance measures.

With an effective QAPI program, the dialysis facility can identify and reinforce the activities that it is performing well and seek and respond to opportunities for improvement on a continuous basis. We intend that as a result of this proposed requirement the facility itself will be the catalyst that precipitates continuous improvements. The dialysis facility may choose to inform their patients of facility's quality improvement activities and may want to engage patients who are dialyzing in their facility of these activities. The patient's role in achieving quality improvement goals in areas such as adequacy of dialysis and vascular access should be acknowledged. Partnering with the patients to make improvements may be an important aspect of a successful QAPI program.

The proposed QAPI Condition discussed in this section of the preamble encompasses a facility's internal approach to improving the quality of dialysis care. We are considering putting into place, within these conditions, minimum clinical standards that would serve as external stimuli for further improvements in the quality of dialysis services. The following is a discussion of how minimum clinical standards could be implemented and specific areas for which we are soliciting public comment.

4. Facility Specific Standards for Enforcement

In this proposed rule, we have discussed and taken an approach to quality assurance that relies exclusively upon the facility's own process for setting, monitoring, and maintaining clinical standards as the basis for evaluating its performance. This approach is consistent with our overall approach to quality improvement. However, dialysis care is provided in as homogeneous a medical context as any service and may well be susceptible to measurement against baseline clinical expectations.

The OIG's Report of 2000 on *External Quality Review of Dialysis Facilities: A Call for Greater Accountability* encourages the use of standardized performance measures to hold individual facilities accountable for quality of care. OIG also recommends an approach that reflects a balance between collegial and regulatory modes of oversight. Their report addresses the use of standardized performance measures both to engage in quality improvement activities and to enforce minimum standards.

Supporters of an approach requiring adherence to clinical standards for ESRD facilities argue that: (1) There is specificity and relative homogeneity in the services delivered; (2) there are significant risks to patient safety if care is not delivered appropriately; (3) the renal community has been proactive in defining and using clinical standards; (4) there are correlations between having acceptable NKF–K/DOQI-derived measures for adequacy of dialysis and anemia and positive outcomes for individual patients; and (5) the data systems supporting ESRD program operations are comprehensive and unique.

We are soliciting comments on the feasibility of using commonly agreed-upon clinical standards in our requirements and enforcement efforts. In setting the minimum clinical standards for performance, we would use selected clinical practice guidelines developed by the NKF–K/DOQI, which were developed with broad community input and consensus, and have gained extensive national and international acceptance. We would initially establish minimal expectations about adequacy of dialysis rates and anemia levels, but we would continuously look to science for updated standards.

The method for applying these standards would be to require that a dialysis facility must maintain minimum clinical standards (that is, adequacy of dialysis and anemia levels) for all patients. If the patient's outcomes did not meet the clinical expectations, the interdisciplinary team would be required to make adjustments. If the patient is unable to achieve the minimum expected clinical outcomes, a member of the interdisciplinary team would need to enter an explanation in the patient's medical records. If the minimum expected clinical outcome is achievable but is not being achieved, the interdisciplinary team would be expected to develop and implement an improvement program to achieve and maintain the expected outcome.

We would periodically establish our requirements and publish them in the **Federal Register**. The standards that we would use if this approach were adopted are as follows:

- The minimum delivered threshold for Kt/V is—

—1.2 (single pool) for hemodialysis patients (as specified in the NKF–K/DOQI Clinical Practice Guidelines For Hemodialysis Adequacy: Update 2000, Guideline 4);

—1.7 (weekly) for continuous ambulatory peritoneal dialysis patients (as specified in the NKF–K/DOQI Clinical Practice Guidelines for Peritoneal Dialysis Adequacy: Update 2000, Guideline 15);

—2.1 (weekly) for continuous cycling peritoneal dialysis patients (as specified in the Peritoneal Dialysis Adequacy: Update 2000, Guideline 16); and

—2.2 (weekly) for intermittent peritoneal dialysis patients (as specified in the Peritoneal Dialysis Adequacy: Update 2000, Guideline 16).

- For anemia management, the minimum required levels would be—

—A hemoglobin level of 11 gm/dL (as specified in the NKF–K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2000, Guideline 4); or

—A comparable hematocrit of at least 33 percent (as specified in the NKF–K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2000, Guideline 4).

To make this approach work, we would need to address and mitigate the disadvantages that arise from assigning minimum numerical target values. We would be required to go through a rulemaking process each time we wanted to update the numerical values to correspond with any scientific advances. NKF–K/DOQI clinical practice guidelines for adequacy of dialysis and anemia are designed for assessing individual patient care based on individual patient characteristics. We would need to address the issue of using these as measures for facility-wide performance. Can this effectively be done or would a risk adjustor need to be developed to avoid disadvantaging facilities that have a different case mix? We are also soliciting comments on methods for using current NKF–K/DOQI clinical practice guidelines as facility-wide measures. For example, comments on the use of the statistically based threshold measures of performance would be especially helpful. Under such an approach, facilities in which a predetermined portion of patients fail to

meet the selected clinical standards over some period of time, using a standard deviation, percentile-based, or some other method, need to develop a corrective action plan. We are specifically soliciting comments on this issue.

If we were to codify a clinical standards condition, the text would read as follows:

Condition: Clinical Standards

The dialysis facility must maintain minimum clinical standards for all patients. If the patient's care does not meet such standards, the interdisciplinary team must make adjustments. If the patient is unable to achieve the minimum expected clinical outcomes, a member of the interdisciplinary team must provide an explanation in the patient's medical records. If the minimum expected clinical outcome is achievable but is not being achieved, the interdisciplinary team must develop and implement an improvement program to achieve and maintain the patient's expected level of general health.

Standard: Performance Expectations

(a) *Dose of dialysis.* The interdisciplinary team must assist and support facility patients in achieving and maintaining the expected dose of dialysis as specified by the Secretary and published in accordance with the notification requirements in paragraph (d)(i) of this section.

(b) *Anemia.* The interdisciplinary team must assist and support facility patients in achieving and maintaining the expected hematocrit/hemoglobin level as specified by the Secretary and published in accordance with the notification requirements in paragraph (d)(i) of this section. The patient's hematocrit/hemoglobin levels must be measured at least monthly.

(c) *Additional clinical standards.* Facilities are responsible for assuring that their patients achieve at least a minimum performance level on additional clinical standards that may be selected by the Secretary. The methodology and minimum performance expectations will be determined in accordance with the NTTAA guidelines.

(d) *Notification.* CMS will publish a **Federal Register** document that proposes or finalizes—

(i) The current minimum expected outcomes for dose of dialysis and anemia referenced in paragraphs (a) and (b) of this section.

(ii) Other standards upon development and acceptance of the standards by the Secretary.

F. Condition: Special Purpose Renal Dialysis Facilities (Proposed § 494.120)

[If you choose to comment on issues in this section please include the caption ''Special Purpose Renal Dialysis Facilities'' at the beginning of your comment.]

Special purpose renal dialysis facilities are dialysis units approved on a short-term basis (currently, for no more than 8 months) to provide dialysis services to a group of patients otherwise unable to obtain treatment in the geographic area served by the facility.

The existing requirements for special purpose renal dialysis units are in § 405.2164. That section states that special purpose units must comply with the conditions specified at §§ 405.2130 through 404.2164, with the exception of §§ 405.2134 to 405.2137 (that is, conditions relating to participation in network activities and the patient long-term care program). Existing § 405.2164(b) requires a special purpose facility to consult with the patient's physician to ensure that care provided is consistent with the care plan and long-term care plan required in existing § 405.2137. Existing § 405.2164(c) requires the ''period of approval'' (that is, Medicare certification), not to exceed 8 calendar months.

In the May 11, 1983 **Federal Register** (48 FR 21254), we published a final rule that provided for time-limited approval of special purpose renal dialysis facilities. These facilities were established for two purposes: (1) To serve ESRD patients in a vacation area (such as a vacation camp) when the area is too remote from existing approved facilities to allow convenient access by patients; or when a convenient approved facility does not have sufficient available capacity to serve a number of vacationing patients; and (2) to serve ESRD patients on an emergency basis when approved permanent facilities close due to natural disasters, strikes, or bankruptcies, and the backup facilities in the area cannot accommodate the patients of the closed facilities. In the May 11, 1983 final rule, the last provision was added specifically, ''to ensure continuous access to care in the event that an approved permanent facility is closed because it cannot achieve adequate revenues under the prospective reimbursement system.'' The certification period of 8 months was determined to be appropriate in response to public comments urging that the original temporary certification proposal (of 6 months) be extended.

Following the publication of the May 11, 1983 final rule, we developed a certification and approval process and a separate series of provider numbers for ESRD facilities approved as special purpose renal dialysis facilities.

In our deliberations regarding any possible revisions to this condition, we found that very few vacation camps have requested approval for certification as special purpose renal dialysis facilities. In March 2001, for example, Medicare records indicated that only one vacation camp in the United States was certified as a special purpose renal dialysis facility. We now question whether the requirements for vacation camp renal facilities to be certified as a special purpose renal dialysis facility are too onerous.

A search on the web lists 36 camps for ESRD patients throughout the United States. Some of the camps do not accept hemodialysis patients or accept hemodialysis patients for weekend only camps. These camps do not have a need for hemodialysis services. Other camps provide transportation to a certified hemodialysis facility off the campgrounds. Since the number of United States certified hemodialysis facilities has doubled in the last decade to approximately 4,000, transporting campers to a nearby dialysis facility may be feasible in many locations. It is not clear whether there remains a need to continue to establish vacation camp special purpose renal dialysis facilities in the conditions for coverage.

However, we are proposing to retain this condition in order to address the possible needs of patients who, as a result of the emergency conditions listed above, or participation in a remote vacation camp, need dialysis services on a short-term basis, and to ensure that facilities providing this type of care are properly certified for participation in the Medicare program. We are also proposing to reduce the burden of the requirements that a vacation camp must meet in order to be certified as a special purpose renal facility. Vacation camps generally operate during the summer months, when schools are closed, and usually offer sessions lasting up to 2 weeks. The task of meeting the ESRD conditions for coverage in order to offer a few camp sessions each year (with the exception of the conditions relating to participation in network activities and the patient long-term care program), may deter vacation camps from providing hemodialysis services and seeking Medicare certification.

Therefore, we are proposing in § 494.120 that a special purpose renal dialysis facility would be approved to furnish dialysis at special locations, that is, vacation camps that serve ESRD patients in a temporary residence, or

facilities established to serve ESRD patients under emergency circumstances. A vacation camp must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients.

Proposed § 494.120(a) maintains the 8-month approval period in the existing § 405.2164(c). In view of the history of the few Medicare-certified special purpose dialysis facilities, we believe a 8-month approval period is adequate.

Proposed § 494.120(b) would retain the existing service limitation requirement (specified in § 405.2164(d)) that limits the special purpose unit to providing services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

In addition, we are proposing in § 494.120(c)(1) that a special purpose renal dialysis facility would be approved as a vacation camp by demonstrating compliance with the following standards and conditions for coverage:

- Infection control (§ 494.30)).
- Water quality (§ 494.40); if the facility uses home portable water treatment systems, the facility would instead comply with the provision regulating home monitoring of water quality (§ 494.100(c)(1)–(v)).
- Reuse of hemodialyzers and other dialysis supplies if reuse is performed (§ 494.50).
- Patients' rights (§§ 494.70(a) and (c)).
- Laboratory services (§ 494.130); a facility would be required to have a plan for obtaining laboratory services for cases when it is necessary for patient safety.
- Medical director responsibilities for patient care policies and procedures (§ 494.150(c) and (d)).
- Medical records (§ 494.170).

We are proposing in § 494.120(c)(2) to specify that a special purpose renal dialysis facility certified due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility and is approved by demonstrating compliance with § 494.120(c)(1) and the following additional conditions:

- Compliance with Federal, State, and local laws and regulations (§ 494.20).
- Physical environment (§ 494.60).
- Patients' rights (§§ 494.70(a) through (c)).
- Personnel qualifications (§ 494.140).
- Medical director (§ 494.150).
- Governance (§ 494.180).

While the certification of a special purpose unit is time-limited and the patient's treatment in the unit will be limited, we believe that every effort must be made to ensure that the quality of care provided is comparable to that provided to any dialysis patient in a Medicare-approved unit. However, we believe requiring compliance with any additional requirements would be too burdensome for a special purpose unit.

We are proposing in § 494.120(d) to retain the existing requirement that a special purpose unit consult with the patient's physician, with an added provision that this consultation must occur before the initiation of dialysis in the special purpose unit. This provision is added to ensure that the special purpose unit is fully aware of the patient's current medical condition and that the special purpose unit can provide dialysis services consistent with the patient's plan of care described at § 494.90.

In addition, we are proposing in § 494.120(e) to require the special purpose unit to document care provided to the patient and forward that documentation to the patient's regular dialysis facility within 30 days of the last scheduled treatment in the special purpose unit.

We are soliciting comments on whether vacation camps should continue to be included under the special purpose renal dialysis facility condition for coverage.

G. Laboratory Services (Proposed § 494.130)

[If you choose to comment on issues in this section please include the caption ''Laboratory Services'' at the beginning of your comment.]

In 1994, we revised existing § 405.2163 to stipulate that the dialysis facility must make available laboratory services (other than tissue pathology and histocompatibility) and that all laboratory services must be performed by an appropriately certified laboratory in accordance with the Clinical Laboratory Improvement Amendments (CLIA) regulations at 42 CFR 493. Existing § 405.2163(b) also requires a dialysis facility that furnishes laboratory services to furnish these services in accordance with applicable requirements established for certification of laboratories under the CLIA. Independent dialysis facilities must be certified under CLIA to perform and bill most laboratory tests to the Medicare program. This section also allows a dialysis facility that does not provide laboratory services to make arrangements to obtain these services with a laboratory certified under CLIA.

We are proposing in § 494.130 to retain the existing requirements governing laboratory services in § 405.2163(b) without change.

VI. Provisions of Proposed Subpart D: Administration

A. Personnel Qualifications (Proposed § 494.140)

[If you choose to comment on issues in this section please include the caption ''Personnel Qualifications'' at the beginning of your comment.]

The existing personnel qualifications of dialysis facility staff can be found in § 405.2102. Those requirements list the education and experiential requirements for chief executive officers, physician-directors, nurses responsible for nursing services, dietitians, medical records practitioners, transplantation surgeons, and social workers.

In existing § 405.2102(e), a physician-director must be board eligible or board certified in internal medicine or pediatrics with at least 12 months of experience or training in the care of patients at ESRD facilities.

Existing § 405.2102(d) defines the nurse ''responsible for nursing service'' as a person who is licensed as a registered nurse by the State in which practicing, with at least 12 months experience in clinical nursing, with at least 6 months experience in nursing care of patients with permanent kidney failure or patients undergoing kidney transplantation, or 18 months of experience in nursing care of the patient on maintenance dialysis. This section also states that if the same individual is assigned responsibility for self-care dialysis training, that individual must have at least 3 months experience in training ESRD patients for self-care.

Existing § 405.2102(b) defines a dietitian as a person who—

- Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976 and has at least 1 year of experience in clinical nutrition; or
- Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics and at least 1 year of experience in clinical nutrition.

Existing § 405.2102(f) defines a social worker as a person who is licensed in the State in which practicing, has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school accredited by the Council on Social Work Education, or has served for at least 2 years as a social worker with at least 1 year in a dialysis or

transplantation program before September 1, 1976 and consults with a social worker holding a masters degree.

ESRD is an extremely complex disease requiring highly technical and complex treatment, and patients with this disease have special needs that require highly specialized care that can only be provided by qualified personnel. As the demographics of the dialysis population continue to change, producing a more elderly patient population with more co-morbid conditions, direct patient care needs and the skill needed to meet those needs will continue to increase. Also, as we move away from unnecessary process and procedural requirements in the conditions for coverage towards better patient outcomes, it becomes even more important to have qualified, experienced, and well-trained staff to achieve the targeted clinical outcomes for each patient.

In the past, industry representatives have supported the retention of minimum personnel qualifications in the conditions, and we are proposing to retain most of the existing personnel qualifications requirements in this proposed rule. We are also proposing changes where we believe they are needed, and those changes are discussed in the preamble discussion that follows.

In § 494.140, we are proposing to consolidate all of the personnel qualifications requirements into a single condition, entitled ''Personnel qualifications.'' In addition, proposed § 494.140 would require that a dialysis facility's staff (whether employees or contractors) meet the personnel qualifications and demonstrated competencies necessary to serve the general needs of its patients. We also propose that the dialysis facility's staff must have the ability to sustain and demonstrate the skills needed to perform the specific duties of their positions.

We recognize that facilities are not always able to directly employ individuals to perform all required services; and therefore, facilities may continue to furnish services through qualified personnel by arrangement. Any position in a facility may be filled by a contracted employee, but the contracted employees must meet the personnel requirements as well as the demonstrated skills and competencies in proposed § 494.140 to ensure that patients receive quality care from all personnel.

The expected outcome is the coordinated, comprehensive interdisciplinary delivery of appropriate and effective services provided by skilled professionals. These professionals would meet the requirements in this proposed rule and would adhere to the facility's policies and procedures. The dialysis facility has the flexibility to assign specific duties to each staff member (either employee or contractor) who provides services in the facility, as long as the required outcomes required are being met.

1. Medical Director (Proposed § 494.140(a))

In proposed § 494.140(a) we would maintain some of the qualification requirements for a physician director. However, we propose to change the word ''physician'' to ''medical'' to be consistent with current standards of practice in the industry. The medical director of a facility is responsible for the development of patient care policies and the delivery of services. For this reason, we chose to require that the medical director be trained in nephrology and have experience in the care of dialysis patients to emphasize the need for experience in managing dialysis care and associated medical conditions. The medical director of a dialysis unit must have a thorough knowledge and understanding of the complexity of ESRD and its effects on the dialysis patient.

The existing regulation at § 405.2102 requires that the director of the facility be either board certified or board eligible. There has been considerable disagreement within the medical community as to whether board certification or eligibility is an important indicator of professional competence. In view of the diversity of opinion in the industry and the absence of any indication that the quality of care would decline if this requirement were deleted, we are proposing to eliminate the requirement that the medical director be either board certified or board eligible. Thus, we propose to require only that the medical director be a physician who has completed a board-approved training program in nephrology and has at least 12 months experience providing care to patients receiving dialysis. We are retaining the alternate option for situations when a physician who meets this criterion is not available that allows another physician to direct the facility, subject to the approval of the Secretary. In the absence of a compelling reason for maintaining the grandfathering provision for the physician director under § 405.2102(e)(2), we have not incorporated this provision in our proposed personnel qualifications for the medical director at § 494.140(a).

2. Nursing Services (Proposed § 494.140(b))

In § 494.140(b) we propose a Nursing Services standard that would include the necessary qualifications for 4 nurse categories: (1) The nurse responsible for nursing services in the facility; (2) the nurse responsible for training in self-care; (3) the charge nurse with responsibility for each patient shift; and (4) any nurse who provides care and treatment in the unit.

We are proposing in § 494.140(b)(1)(i) to retain the existing requirement at § 405.2162(a) that each facility employ at least 1 full time qualified nurse responsible for nursing service in the unit. In proposed § 494.140(b)(1)(ii) and (iii) we would maintain the existing requirements that the nurse responsible for nursing services in the unit be a registered nurse who meets the practice requirements of the State in which he or she is employed, and has at least 12 months of experience in clinical nursing with an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

We are proposing in § 494.140(b)(2) to specify the requirements for the nurse responsible for training in self-care. For a detailed discussion of these nursing requirements see section V.D.1. of this preamble.

We are proposing in § 494.140(b)(3)(i) to retain with minor modifications the existing requirement at § 405.2162(b)(1) that the individual responsible for each shift be a licensed health professional such as a registered nurse (RN) or a licensed practical nurse (LPN) who meets the practice requirements of the State in which he or she is employed. We recognize that in some instances, a licensed practical nurse is able to demonstrate the knowledge, training, and experience to serve as the charge nurse in a dialysis unit and this is currently the practice in some units. In proposed § 494.140(b)(3)(ii) we would specify that the charge nurse must have at least 12 months experience in nursing care, including 3 months of specialized experience in providing clinical nursing care to patients on maintenance dialysis.

We are proposing in § 494.140(b)(4) that each nurse who provides care and treatment to patients must be either a registered nurse or a licensed practical nurse who meets the practice requirements of the State in which he or she is employed.

3. Dietitian (Proposed § 494.140(c))

Renal dietitians are important and necessary members of the patient's interdisciplinary care team. Some of the

responsibilities of the renal dietitian are: (1) Counseling patients on management of protein, sodium, potassium, phosphorus, and fluid controlled diets, translating the chemistry of these limits into meals for patients; (2) monitoring vitamin and mineral supplementation, including iron levels and their effect on erythropoietin; (3) managing glycemic control of diabetic patients by manipulation of diet; and (4) assessing nutritional status by using clinical and biochemical measures.

We believe that these kinds of activities will require a dietitian with specialized experience in clinical nutrition. The specialized training and experience would ensure that dialysis facilities have a dietitian knowledgeable about medical nutrition therapy, physiology, and food composition. This specialized knowledge is critical if a dietitian is to effectively manage the complex tasks necessary in treating a dialysis patient, so the patient is able to manage his or her own disease.

We are proposing in § 494.140(c) to retain requirements comparable to the existing requirements laid out under the definition of ''qualified personnel'' at § 405.2102(b). We propose that the dialysis facility dietitian be a registered dietitian with the Commission on Dietetic Registration, the official credentialing agent for the American Dietetic Association. We also propose that the dietitian meet the practice requirements of the State in which he or she is employed and have a minimum of 1 year of professional work experience in clinical nutrition as a registered dietitian in order to qualify to perform the special responsibilities of renal dietitians discussed above.

4. Social Worker (Proposed § 494.140(d))

We are proposing in § 494.140(d) to retain the existing requirements for social workers at § 405.2102(f), except for the ''grandfather clause'' which exempted individuals hired prior to the effective date of the existing regulations (that is, September 1, 1976) from the social work master's degree requirement and substituted an experience criterion, which is 1 year in a dialysis setting; and a criterion requiring including a consultative relationship with a social worker with a master's degree. Since this clause only applied to social workers without a master's degree, already employed in a dialysis or transplantation setting as of 1975, we question whether there is any need to retain it.

We recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. Since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we believe qualified master's degree social workers (MSW) trained to function autonomously are essential. Social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. The dialysis patient needs psychosocial evaluations, a treatment plan based on the patient's current psychosocial needs, and direct social work interventions. Facility social worker services include counseling services, long-term behavioral and adaptation therapy, and grieving therapy. We believe that MSW training provides the necessary education and experience in these areas. We have removed the requirement for specialization in clinical practice, because this designation is not available in all States and may prove to be a barrier to social workers entering practice in the dialysis arena.

While nonprofessional personnel may serve in a supportive capacity, we do not believe they can be employed in place of a fully-credentialed MSW. We recognize that dialysis patients also need other essential services including transportation and information on Medicare benefits, eligibility for Medicaid, housing, and medications, but these tasks should be handled by other facility staff in order for the MSW to participate fully with the patient's interdisciplinary teams so that optimal outcomes of care may be achieved.

5. Dialysis Technicians (Proposed § 494.140(e))

There are no Federal requirements for dialysis technicians in the existing ESRD conditions for coverage with the single exception of reuse technicians, who are covered by the AAMI guidelines. When the existing conditions for coverage were published in 1976, dialysis technicians were an emerging occupation. At that time it was common for one nurse to provide dialysis care to two dialysis patients at a time. Currently, dialysis patient care technicians are the primary caregivers in most facilities and it is not unusual for a single technician to provide dialysis care to three or four patients at a time.

The discussion that follows applies primarily to dialysis technicians who provide direct patient care. Training and other requirements for reuse technicians are described in specific sections of the AAMI guidelines, which have been incorporated by reference in existing § 405.2150(a)(1) and in this proposed rule (*see* § 494.50).

As we researched this issue, we reviewed past and current efforts by the States to regulate dialysis technicians. The States are currently using a variety of approaches and methodologies to regulate dialysis technicians, including minimum qualification requirements, mandatory competency testing, registration, licensure, and certification. We also looked at the typical scope of practice for this occupation in dialysis facilities, and took into account the public policy positions and statements from national associations and organizations that advocate uniform Federal guidelines for dialysis technicians.

Arizona, Ohio, and Oregon now require dialysis technician certification via a nationally standardized examination. California and Texas require specific training and testing, but allow a nationally standardized certification examination to be substituted for their training and testing requirements. Georgia identifies a standardized training program for hemodialysis patient care technicians (PCTs), but does not require technicians to pass a national certification test unless a facility's training program fails to provide adequate training. The three organizations that provide nationally recognized standardized certification examinations are listed later in this section of the preamble.

Other States including Connecticut, South Dakota, Kentucky, Utah, Virginia, Washington, New Mexico, and the District of Columbia require certain training and competencies for dialysis technicians. States with past or ongoing efforts to regulate the practice of unlicensed dialysis technicians and technical staff include Colorado, Illinois, Louisiana, Maryland, New York and Oklahoma.

Some national associations (for example, the American Nephrology Nurses Association (ANNA) and the National Association of Nephrology Technicians (NANT)) have advocated uniform training and certification requirements for dialysis technicians for several years and continue to advocate for these measures at the State and national level. Their primary concern is to ensure that care is provided by qualified and trained health care workers who are able to demonstrate the necessary competencies to perform the assigned duties of their positions.

Since 1990, NKF's Public Policy Board has been interested in evaluating and defining the proper role of, and training needed by, dialysis technicians. In 1992, NKF's Dialysis Technician Task Force published an extensive list of tasks that define the ''patient care role description'' as well as the appropriate areas of required training (NKF, pp. 229–232). The authors of that article advocated, among other things, that technicians should have at least a high school diploma or equivalency; take training courses in the basic sciences; report directly to a registered nurse; and be able to effectively perform specific tasks, subject to individual State licensure and scope of practice laws and regulations. The article also recommended a basic training course curriculum for renal technicians which included, among other things: (1) An introduction to dialytic therapies; (2) principles of hemodialysis; (3) the effects on the patient of kidney failure; (4) dialysis procedures; (5) hemodialysis devices; (6) water treatment; (7) reprocessing (if applicable); (8) patient education; (9) infection control; and (10) the techniques used in quality assurance and continuous quality improvement.

The adverse outcomes for dialysis patients of improper care from inadequately trained dialysis technicians could include blood leaks, access damage, incorrect dialysis concentrate, infection, and hypotension. Increased numbers of patient hospitalizations, which in turn result in higher costs to both public and private payers, could also be a direct outcome of poor patient care from dialysis technicians.

In most dialysis facilities, renal technicians now provide a large percentage of direct patient care services. In most instances, care is provided under the supervision of a registered nurse. However, the degree of supervision and the technician-to-patient ratio will often vary from facility to facility.

A wide variety of tasks are performed by dialysis technicians, depending on the limitations of State law. These tasks include, but are not limited to the following:

- Preparing dialysis apparatus.
- Performing equipment safety checks.
- Initiating dialysis (including cannulation and venipucture with large gauge needles).
- Intravenous administration of heparin and sodium chloride solutions.
- Subcutaneous or topical administration of local anesthetics in conjunction with placement of fistula needles.
- Intraperitoneal administration of sterile electrolyte solutions and heparin for peritoneal dialysis.
- Monitoring patients during dialysis.
- Taking vital signs.
- Documenting tasks and patient observations.
- Equipment maintenance and repair.
- Water systems monitoring and maintenance.
- Quality control measures.
- Inventory.

One of the options we considered was requiring certification for dialysis technicians. Certification is a voluntary process by which recognition is granted to an individual who has met certain qualifications. Certification is typically awarded upon the successful completion of an approved competency examination. The goal would be a national, standardized requirement for education, training, and competency testing for dialysis technicians. In considering this option, we noted that some States have chosen to develop their own competency examinations or to recognize competency examinations prepared and administered by one of the three national organizations that provide competency testing and certification for dialysis technicians. Those organizations are the Nephrology Nursing Certification Commission (NNCC), the Board of Nephrology Examiners Nursing and Technology (BONENT), and the National Nephrology Certification Organization (NNCO). The common goal of these organizations is to administer an effective test that serves as a basis to certify technicians for initial or more advanced competencies in knowledge, skill and abilities.

In our deliberations on whether to propose Federal requirements for dialysis technicians engaged in direct patient care, we are reminded that Medicare has had a longstanding policy of respecting State control and oversight of health professionals. The Congress has left this licensure function to the States and Medicare recognizes State-defined scope-of-practice laws under which health care professionals are licensed in the United States.

After careful consideration, we do not believe it would be prudent to propose a national certification requirement for dialysis technicians at this time. We take this position for several reasons. First, there is no consensus within the renal community regarding the efficacy of technician certification to produce improved patient outcomes of care. Second, there is no standardized national certification test at this time, and the individuals and organizations, including the States, who advocate or have adopted certification are not in agreement regarding which certification test is the most effective. Some States have designed, or are in the process of designing, their own competency examinations, while others have recognized one or more of the existing examinations as evidence of compliance with their requirements. Finally, a Federal certification requirement entailing mandatory competency examinations would necessitate additional costs for transportation, lodging, fees, and preparatory materials associated with the examination. Those costs would have to be borne by either the individuals seeking certification, the dialysis facilities, or both. Without clear evidence that certification would produce better patient outcomes, we are reluctant to propose any new requirements that would drive up costs for technicians in current practice, dialysis facilities, or both. Therefore, for these reasons, we believe it is more prudent at this time, not to propose a national certification requirement for dialysis technicians. Instead, we are proposing in § 494.140(e) a set of minimum qualifications for dialysis technicians that will include a minimum education requirement, minimum requirements for on-the-job training and experience, and proposals for the composition of an effective technician-training program.

We are proposing in § 494.140(e)(1) to specify that dialysis technicians meet all applicable State requirements (for example, credentialing, certification, and licensure) in the State in which they are employed. As stated above, we believe technicians in any Medicare-approved facility should comply with any existing State requirements for their profession.

In proposed § 494.140(e)(2) we would require dialysis technicians to have at least a high school diploma or equivalency. We are proposing this criterion for two reasons. First, some of the States that regulate dialysis technicians (for example, Connecticut and Ohio) require dialysis technicians to have a high school education or equivalency.

Second, other States (for example, Texas, California, Oregon, and New Mexico) that require (among other options) certification by one of the national certification organizations (that is, NNCC, NNCO, BONENT) also require a high school diploma or equivalency because that is a prerequisite for taking the certification examination. We concur with the position taken by States that regulate dialysis technicians and the national technician certification organizations because we believe a

minimal education requirement is appropriate and necessary to enable an individual to complete the wide variety of patient care functions.

We are proposing in § 494.140(e)(3) to require that each technician complete at least 3 months experience, following the facility's training program (also required by § 494.180(b)(5)). This experience must be gained under the direct supervision of a registered nurse with a focus on the operation of kidney dialysis equipment and machines and providing direct patient care with particular sensitivity to the management of difficult patients. We see dialysis technician training as a cycle that proceeds from written instruction that would provide a basic foundation of knowledge, to a necessary period of on-the-job training under the supervision of a knowledgeable professional trained in all aspects of patient care, including medical emergencies.

While written instruction is essential, we also believe properly supervised on-the-job training must follow to allow the technician to take maximum advantage of the information provided in the training program before the dialysis technician is allowed to provide direct patient care with minimal supervision. We believe 3 months of effective on-the-job, supervised training is necessary before a technician is permitted to care for patients without close and direct supervision.

We have made this proposal for several reasons. As discussed in section VI.A.2 of this preamble, a registered nurse has the necessary professional training and expertise to coordinate care in the unit, perform patient assessments, respond to clinical questions from staff and patients, and coordinate ongoing care. Dialysis technicians, as the primary caregivers in most dialysis units, function as extensions of the unit's professional nursing staff. We believe it is essential that a unit's registered nurse provide the ''hands-on'' direct supervision to impart this training to new dialysis technicians. For example, in the patient outcomes environment these regulations are designed to encourage, it is essential that technicians understand the significance of continuous quality improvement (that is, collecting data, keeping logs, the clinical importance and meaning of target patient outcome measures, and recognizing and reporting medical errors). We also believe a registered nurse can be very effective in instructing new dialysis technicians in necessary aspects of patient care, such as ensuring patient privacy and confidentiality, and demonstrating good interpersonal skills when dealing with patients, including disruptive or challenging patients. In addition, a registered nurse is best equipped, through training and experience, to ensure that every technician can demonstrate the basic skills needed to provide routine patient care (for example, initiating, monitoring, and terminating dialysis; proper aseptic techniques; recognizing and reporting medical errors; and dealing with medical emergencies). For all of these reasons, we believe a 3-month period of direct supervision by a registered nurse is essential to ensure patient health and safety and to ensure that dialysis technicians that provide direct patient care can do their part to ensure that the unit meets its patient outcomes goals. We invite comments on the 3-month training proposal.

We are proposing implementation of a training program that is specific to technicians who monitor the water treatment system. Water purity is important to protecting patient safety and the water must be adequately monitored and properly collected for testing as specified at proposed § 494.40. The technician who carries out water testing and monitoring of the water treatment system must be appropriately trained following a program that has been approved by the medical director and governing body. Typically, facility patient care technician training programs contain a water treatment system training module. This module may form the basis of a training program that could be used to train a water treatment technician.

6. Other Personnel Issues

Existing § 405.2136(f)(1)(vi) requires the facility have patient care policies that cover pharmaceutical services. There is currently no Federal requirement for a pharmacist to play a role on the multidisciplinary team within the dialysis facility. The dialysis facility generally has some access to the pharmacist who is dispensing outpatient medications to the dialysis patient. A hospital-based dialysis unit might be able to use the hospital pharmacist as a resource. There may also be limited pharmacy resources available to the average dialysis facility that is administering intravenous drugs and making adjustments to a patient's medication regimen. It has been suggested by some in the renal community that there should be a requirement within the proposed conditions for coverage for each dialysis facility to ensure a routine assessment of patient medications by a pharmacist. The reasons for this recommendation are: (1) Most dialysis patients take an average of 12 medications, which increases the risk of adverse drug events; and (2) the patients' have complex pathophysiology, which affects how medications can be used safely (Kaplan, pp. 316–319). There are a number of publications that describe the contributions of pharmacists to the improved care of various patient populations while simultaneously reducing medication-related costs.

Therefore, we have proposed, as part of the new patient assessment condition at § 494.80(a)(3), that facilities conduct a laboratory profile and medication history on each patient as part of their comprehensive patient assessment. However, we have not proposed a specific requirement for pharmaceutical services. We invite comments regarding what role, if any, the pharmacist should play within the dialysis facility as well as the facility's appropriate responsibility for pharmaceutical services and the efficient use of medications in the new conditions for coverage.

B. Condition: Responsibilities of the Medical Director (Proposed § 494.150)

[If you choose to comment on issues in this section please include the caption ''Responsibilities of the Medical Director'' at the beginning of your comment.]

The requirements for the director of a renal dialysis facility are found in existing § 405.2161. Section 405.2161 requires the director to be a physician who devotes sufficient time to his or her director responsibilities to plan, organize, conduct, and direct the professional ESRD services of the facility. Existing § 405.2161 also states that the physician-director may also serve as the chief executive officer (CEO) of the unit.

Existing § 405.2161(a) states that the director must meet the qualifications described in § 405.2102 (that is, be board eligible or board certified and have at least 12 months of experience or training in the care of patients in ESRD facilities). Existing § 405.2161(b) requires the physician-director to: (1) Participate in the selection of a suitable treatment modality for all patients treated in the unit; (2) assure adequate training of nurses and technicians in dialysis techniques; (3) assure adequate monitoring of the patient and the dialysis process, including periodic monitoring of self-dialysis patients; (4) assure the development of a patient care policy and procedures manual and its implementation; and (5) assure that patient teaching materials are made available for self-dialysis and home dialysis patients.

The June 2000 OIG Report was an extensive review to ascertain our effectiveness in monitoring the ESRD program. The report contained several recommendations regarding ways we should revise the ESRD conditions for coverage in order to strengthen the accountability of dialysis facilities that participate in the Medicare program. One of those recommendations was to reinforce the accountability of the dialysis facility's medical director for the provision of patient care. Specifically, the report stated the following: ''While the governing body of the facility is the basic source of accountability, the medical director should clearly be empowered as the on-site agent most directly responsible for the quality of care being delivered. In this capacity, the medical director should clearly have the authority to develop and monitor quality improvement efforts, to serve as an educational resource for medical and nursing staff, and, when individual staff are not performing adequately, to bring that to the attention of the facility's designated governing authority.''

In response to the OIG's recommendations, we are proposing in § 494.150 to retain medical director as a separate condition for coverage and strengthen the medical director's role. Section § 494.150 would require each dialysis facility to have a medical director who meets the qualifications for that position at § 494.140(a) and who is responsible for the delivery of patient care and patient outcomes in the facility.

We are proposing in § 494.150(a) to assign the operational responsibility for the facility's quality assessment and performance improvement (QAPI) program (§ 494.110) to the medical director. While the facility's governing body is ultimately responsible for allocating the necessary resources (for example, dedicated staff and computers) to establish a QAPI program, we believe the medical director is best qualified to ensure that the facility's QAPI program is effectively developed, implemented, maintained, and periodically evaluated. We are also proposing that the medical director ensure that all clinical staff in the facility, including attending physicians, actively participate in achieving the performance goals and objectives specified in the facility's QAPI program. It is essential for an effective QAPI program that the attending physician and nonphysician staff, who treat patients in the facility, ''buy-in'' to the facility's quality improvement initiatives and actively participate in achieving the facility's QAPI goals. In order for this to happen, we believe the medical director should be given the responsibility to ensure that all staff that treat patients actively participate in the facility's QAPI program. In that capacity we would expect the medical director to make a special effort to educate and encourage facility staff, including attending physician and nonphysician staff, who have not actively participated in the facility's QAPI program. In those rare instances when in-house or attending physician or nonphysician staff will not actively participate in the facility's QAPI program, we would expect the medical director to refer those individuals to the facility's governing body through its CEO or administrator. The governing body (*see* § 494.180) has the final legal responsibility and authority for the operation of the facility and the ultimate responsibility for the facility's compliance with Federal Medicare regulations.

In assuming operational responsibility for QAPI, this requirement emphasizes the importance of the medical director utilizing the best practices within a strong QAPI program. Under this requirement, we would expect the facility's medical director to seek and use comparative data with other facilities when available and use the facility's historical data to demonstrate internal improvements in outcomes over time. This standard also underscores the medical director's ongoing responsibility to ensure that each patient treated in the facility achieves the best possible outcomes of care.

We propose in § 494.150(b) to retain the existing requirement at § 405.2161(b)(2) for the medical director to ensure that staff in the unit are adequately trained. We believe that all patient care personnel in the facility should receive the necessary education and ongoing training to furnish services effectively, efficiently, and completely.

We are proposing in § 494.150(c)(1) to retain the existing requirement § 405.2161(b)(4) for the medical director to assure the development of a ''patient care policies and procedures manual'' for the facility. While our goal throughout this proposed rule has been to eliminate unnecessary process requirements, we believe that a comprehensive patient care policies and procedures manual within a dialysis unit is an essential reference for clinical staff within the unit. The manual is also an opportunity for the medical director to incorporate improved treatment methodologies and current medical practices into day-to-day patient care within the facility in order to ensure better outcomes of care.

We are proposing in § 494.150(c)(1) that the medical director participate in the development, periodic review, and approval of the patient care policies and procedures manual. We are also proposing in § 494.150(c)(2) that the medical director, as the individual with direct responsibility for the manner in which patient care is administered within the facility, be responsible to ensure that these patient care policies and procedures are adhered to by staff who treat patients in the dialysis facility, including attending physician and nonphysician staff. In those instances when facility staff or attending physicians or nonphysicians have not, or will not, follow the facility's written patient care policies and procedures, we would expect the medical director to educate and encourage those individuals to follow facility policies and procedures. In those rare instances when the medical director has been unsuccessful in achieving compliance, we would expect the medical director to refer the matter to the facility's governing body (*see* § 494.180).

We are proposing in § 494.150(c)(2)(ii) that the medical director ensure that the interdisciplinary team follows the facility's patient discharge and transfer policies and procedures described in § 494.180(f). In section VI.E9 of this preamble, we proposed that all patients be informed of a facility's transfer and discharge policies and be given 30 days notice in advance of a facility reducing or terminating on-going care. In addition, we are proposing that the medical director monitor and review each involuntary patient discharge to ensure that the patient's interdisciplinary team has performed the tasks required in § 494.180(f).

In a January 2002 report (Building on the Experiences of Dialysis Corporations, OEI–01–99–0052), the OIG recommended that the ESRD conditions for coverage specify the responsibilities of the Medical Director in situations when there is a quality problem related to an ESRD facility physician. The OIG recommendation follows:

> CMS should also address in the Conditions what medical directors are expected to do when a quality problem is attributable to an attending physician who is not performing adequately. It should make clear that: (1) Medical directors have the authority to conduct or initiate peer review and to address performance problems through directed education, and (2) for more serious situations, the medical director's responsibility to report a physician to an authoritative body, such as the End-Stage Renal Disease Network and/or the State Medical Board.

We are soliciting comments on adding language to this regulation under the Medical Director condition to more specifically state Medical Director responsibilities in regard to ESRD facility attending physicians.

C. Relationship With ESRD Network (§ 494.160)

[If you choose to comment on issues in this section please include the caption ''ESRD Network'' at the beginning of your comment.]

Existing §§ 405.2110 through 405.2113 contain provisions that relate to the designation of the ESRD networks, the functions of the ESRD networks, and the role of the medical review boards. These provisions focus primarily on the role and responsibilities of the ESRD networks, rather than establishing conditions for Medicare coverage that must be met by dialysis facilities. Therefore, we are not incorporating these requirements in the proposed ESRD conditions for coverage. These regulations will remain in part 405 and any revisions will be addressed in a separate notice of proposed rulemaking.

While we believe that the role and responsibilities of the networks do not need to be included in the proposed conditions for coverage, we believe that dialysis facilities must continue to share information with the networks. Thus, we propose to require at § 494.160 that each facility cooperate with the ESRD network serving its designated area in fulfilling the terms of the Network's scope of work contract with CMS, similar to the requirement under existing § 405.2134 concerning participation in network activities. In addition, we believe that this proposed condition pertains directly to the dialysis facility rather than the network and is a condition that a dialysis facility must meet in order to qualify for Medicare approval.

D. Condition: Medical Records (§ 494.170)

[If you choose to comment on issues in this section please include the caption ''Medical Records'' at the beginning of your comment.]

The patient's medical record presents a total picture of the care provided by the dialysis facility. The medical record—

- Serves as an organized plan for treatment and is used for diagnosing, treating, and caring for the patient;
- Facilitates communication among the various health care professionals providing services to the patient;
- Provides a focal point for coordinating the actions of the interdisciplinary team;
- Provides an accurate picture of the patient's progress in achieving care goals;
- Provides the team interdisciplinary members with data for evaluating and documenting the quality and appropriateness of care delivered; and
- Provides evidence of the facility's implementation of policies and procedures relating to patient care.

The existing Medical records requirements at § 405.2139 contain a large number of prescriptive requirements. These requirements include the following:

- Requires that each medical record contain sufficient information to identify the patient, justify the diagnosis and treatment, and document the results accurately.
- Prescribes the content of the medical record to include, for example, patient assessment information, evidence the patient was informed of the assessment, identification and social data, consent forms, medical and nursing history, diagnostic and therapeutic orders, observations and progress notes, laboratory results, and, if necessary, a discharge summary.
- Requires written policies and procedures to protect medical records information.
- Requires the facility to designate a medical records supervisor and includes a list of duties and responsibilities for that individual.
- Requires medical records to be completed promptly and states that all clinical information pertaining to the patient be maintained in a centralized location.
- Requires facilities to maintain medical records in compliance with State laws, or for 5 years in the absence of State requirements.
- Requires a facility to maintain adequate facilities, equipment, and space conveniently located, to provide efficient processing, viewing, filing, and prompt retrieval of medical records.
- Requires that a facility provide for the interchange of medical and other information ''necessary or useful'' in the care and treatment of patients transferred between treating facilities.

In keeping with our goals to eliminate unnecessary requirements and to reduce burden on dialysis facilities, we are retaining only those minimum facility requirements that we believe would be necessary in a patient outcome-oriented environment.

In the proposed medical records condition for coverage (§ 494.170), we would state that the facility must maintain complete, accurate, and accessible medical records on all patients, including home dialysis patients for whom the facility has signed a backup agreement with a DME supplier to provide support services to the patient or whose care is under their supervision. The proposed rule emphasizes that a facility must maintain complete medical records for all patients under its supervision, including home patients.

We propose to no longer prescribe the elements that facilities must include in the patient medical record. Instead, we believe that facilities should have the flexibility to decide what information must be included in the medical record as long as the services provided are consistent with the patient's diagnosed condition. We believe facilities will document patient outcomes (such as Kt/V and hematocrit levels), results of assessments and reassessments (*see* § 494.80), changes in the care plan (*see* § 494.90), and other pertinent information even though the elements are not prescribed, because this information is necessary to track patient progress, implement the patient care plan, record information needed to comply with the patient discharge or transfer procedure (*see* § 494.150(e)), and effectively manage a facility quality assessment and performance improvement program (*see* § 494.110). The patient's plan of care condition (*see* § 494.90(b)) would require the facility to monitor and track patient progress toward the desired outcomes, and inherent in these requirements is the need to document patient results in some form.

We are proposing at § 494.170(a)(1) to retain the existing § 405.2139(b) that requires a facility to protect its patients' medical records against loss, destruction, or unauthorized use because the records are crucial to the patient's care.

However, we propose to eliminate the requirement at § 405.2139(b) that the facility must have written policies and procedures for recordkeeping. We believe this existing requirement is too restrictive and inflexible. The facilities must protect medical record information and keep all patient records confidential. Therefore, as long as there is a system in place to achieve the outcome, we believe that it is not necessary to require the facility to have written policies. However, facilities may find it necessary to have written procedures to ensure that they achieve the expected outcome.

The existing requirement at § 405.2139(b) mandates confidentiality in the handling of patient information

and requires facilities to safeguard patients' records by making them available only to authorized individuals. Under this requirement, a patient may refuse release of records to any individual outside the facility, except in specific situations such as a patient's transfer to another health facility or the release of information required by law.

We are proposing in § 494.170(a)(2) that the patient's medical record be released only under the following circumstances: (1) The transfer of the dialysis patient to another facility; (2) certain exceptions provided for in law; (3) provisions allowed under a third party payment contract; (4) approval by the patient; or (5) inspection by authorized agents of the Secretary as required for the administration of the Medicare program.

We are proposing in § 494.170(a)(3) to maintain the existing requirement at § 405.2139(b) that the facility obtain written authorization of the patient or legal representative for release of information not required or authorized to be released by law.

We are proposing in § 494.170(b)(1) to retain the existing requirement at § 405.2139(d) that current medical records and those of discharged patients are completed promptly. In a dialysis unit, it is essential that each clinical event be documented as soon as possible after its occurrence. Documentation must be current so that the medical records provide an up-to-date picture of the status of the patient at all times. We recognize that stating that medical records should be completed promptly is somewhat vague and subject to interpretation. We invite comments on the addition of a specific timeframe for the completion of patient medical records.

In proposed § 494.170(b)(2) we would maintain the existing requirement at § 405.2139(d) that all clinical information pertaining to a patient is centralized. Regardless of how the medical record is completed and maintained (on paper or electronically), each member of the interdisciplinary team has access to the most recent information on the patient's condition and prescribed treatment.

We are also proposing, in § 494.170(b)(3), that the dialysis facility is responsible for completing, maintaining and monitoring medical records for its Method II home dialysis patients and its other home patients. Under Method II, home dialysis patients elect to receive all equipment and supplies from a DME company. The DME supplier must have a backup agreement with a dialysis facility that provides support services to the patient. We have mentioned Method II specifically in this proposed requirement because Method II requires that the patient's ESRD facility is fully aware of the equipment and supplies being used by the patient in order to accurately update the patient's medical record. Our new focus on achieving better patient outcomes is contingent upon accurate and current medical records for Method II and all other home dialysis patients.

In proposed § 494.170(c), we would make minor revisions to the existing requirement at § 405.2139(e) that medical records be retained for a period of time not less than that determined by State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years or until the patient becomes of age under State law, whichever is longer. The facility's policy for the retention and preservation of records must conform to the requirements of State law or regulations. In this case, the date of discharge means the latest date the patient was discharged from any type of service provided by the dialysis facility.

As previously stated, existing § 405.2139(f) requires the dialysis facility to maintain adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (for example, reviewing, filing, and prompt retrieval) and statistical medical information (for example, required abstracts, reports). The rationale for this requirement was that patient records should be easily retrievable and available to all facility staff and that medical records of patients undergoing treatment should be located close to the treatment area so that no time is lost in obtaining records for review and documentation. Although we agree that patient medical records should be accessible, we do not believe the prescriptive requirements in existing § 405.2139(f) are necessary. As a result, we are proposing to eliminate this requirement. We believe that facilities already provide easy access to all patient medical records to ensure that all staff can promptly retrieve and review patient information.

In § 494.170(d) we are proposing to retain the requirement in existing § 405.2139(g) that requires the facility to provide for prompt transfer of medical information between treatment facilities. The intent of this requirement is to facilitate continuation of care whenever a patient has to either temporarily leave the facility (for example, for vacation or hospitalization) or transfer permanently to a new facility. We believe that it is essential to the continuation of care that a patient's medical history and plan of treatment follow the patient. In addition, we are proposing to require that the facility exchange all medical records within 1 working day. The requirement that information be transferred within 1 working day is in existing § 405.2137(b)(5) (Patient long-term program and patient care plan), which states that if the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day of the transfer. However, we believe the requirement should apply not only to the care plan, but to any medical record information, including, but not limited to, nutritional information, social work services, and rehabilitation status.

Because dialysis patients must receive frequent treatments at prescribed intervals, this proposed requirement would minimize disruption in care. Without the medical information, the patient might receive inappropriate treatment. Requiring that the facility transfer information within 1 working day would minimize the possibility of a breakdown in communication between facilities. It would also ensure that the patient continues to receive care in accordance with his or her designed plan of treatment.

Finally, we are proposing to eliminate the requirement at existing § 405.2139(c) that the facility designate a staff member to serve as the medical records supervisor to facilitate the recordkeeping process. The current functions of the medical record supervisor include, but are not limited to: (1) Ensuring that the medical records are documented, completed, and maintained in accordance with accepted professional standards and practices; (2) safeguarding the confidentiality of the records in accordance with established policy and legal requirements; (3) ensuring that the records contain pertinent medical information and are filed for easy retrieval; and (4) obtaining the services of a qualified medical records practitioner when necessary. In keeping with our goal of eliminating process requirements that are not predictive of good outcomes for patients or necessary to prevent harmful outcomes for patients, we are proposing to eliminate the requirement that a facility designate a medical records supervisor.

E. Condition: Governance (Proposed § 494.180)

[If you choose to comment on issues in this section please include the caption

''Governance'' at the beginning of your comment.]

1. Existing Requirements for Governing Bodies

The existing requirements for the dialysis facility's governing body are found at § 405.2136. Section 405.2136 states that the facility governing body or designated person(s) so functioning has the full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules relative to its own governance and to the health and safety of patients, acts upon recommendations from the Networks, and appoints a CEO who is responsible for the overall management of the facility.

Existing § 405.2136(a) covers the full disclosure of ownership for facilities that are independently owned, controlled by a partnership, or wholly or partially owned by corporate entities.

Existing § 405.2136(b) requires the governing body to develop, delineate, and review annually written operational objectives for the facility. These objectives apply to, among other things, services provided and admission criteria.

Existing § 405.2136(c) requires the appointment of a full-time or part-time CEO who acts as the facility's administrator. The CEO's responsibilities for the operation of the facility include the following:

- Implementing facility policies.
- Coordinating administrative functions.
- Authorizing expenditures.
- Familiarizing staff with facility policies, rules and regulations and applicable Federal, State and local laws and regulations.
- Maintaining and submitting required records and reports.
- Developing, negotiating and implementing contracts.
- Developing and implementing accounting and reporting systems, an annual budget, tracking expenses and revenues, submitting reports;
- Ensuring the facility employs the necessary number of qualified personnel, that those personnel are assigned appropriate duties, and have opportunities for continuing education and related developmental activities.

Existing § 405.2136(d) requires the governing body, through the CEO, to develop and implement personnel policies and procedures, covering, for example, assigned duties, health and safety hazards, supervising trainees, maintaining personnel records for staff, maintaining written personnel policies, orientation and in-service education, and maintaining written personnel manuals.

Existing § 405.2136(e) requires the facility to develop detailed, written arrangements for the use of outside resources, as needed, through its CEO who will serve as a consultant with the responsibility to continually assess performance and use documentation (that is, dated, signed reports).

Existing § 405.2136(f) specifies that the ESRD facility must have written patient care policies, and that policies are—

- Developed by the physician responsible for supervising or directing the provision of ESRD services or the facility's organized medical staff (if there is one) with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care; and
- Approved by the governing body. The governing body is also responsible for periodic review of the implementation of policies to ensure that the intent of the policies is carried out.

Under this section patient care policies must include the following: (1) Scope of services; (2) admission and discharge policies; (3) medical supervision and physician services; (4) patient long-term programs and care plans; (5) medical and other emergencies; (6) pharmaceutical services; (7) medical records; (8) administrative records; (9) maintenance of the physical plant; (10) consultant qualifications and activities; and (11) home dialysis support services. This standard also requires the medical director to execute these patient care policies, schedule hours of operation (when feasible) that are convenient to patients, and evaluate patients' progress toward goals in their long-term programs and care plans.

Existing § 405.2136(g) requires the governing body to ensure that every patient is under the continuing care of a physician and that a physician is available in emergency situations. This standard requires the physician responsible for the patient's care to evaluate the patient's immediate and long-term needs and prescribe a planned regimen of care. The standard also requires the governing body to ensure that there is always medical care available for emergencies with a list of physicians to contact posted at the nursing/monitoring station.

Existing § 405.2136(h) requires the governing body to designate a qualified physician as director of the ESRD facility and establish written policies regarding how medical appointments should be developed, maintained, and if necessary, terminated.

2. Overview of the Proposed Governance Requirements

Consistent with the shift from process-oriented requirements to a more patient-centered, outcome-oriented approach, we are proposing significant revisions to the governance condition. In developing these proposed revisions for the Governance condition we sought to identify requirements that are covered in other parts of this proposed rule, as well as any other redundant, unnecessary or overly burdensome requirements that are unrelated to better patient outcomes. At the same time, we want to retain those structural requirements that might be indicative of better patient outcomes or offer necessary protections to patient health and safety. We also want to be responsive to a recommendation from the OIG (in its June 2000 report) to ''strengthen the accountability of the dialysis facility governing body'' (DHHS/OIG, June 2000). In that report, the OIG made the following recommendation: ''The governing body should be held clearly accountable for the overall quality outcomes provided by the facility. Moreover, since most dialysis facilities are now part of national or multi-national corporations, the governing bodies should ensure that authoritative representatives are readily available to respond to queries and/or visits by State survey agencies or Networks.'' (DHHS/OIG, June 2000.)

We believe that the performance of certain basic organizational functions is a minimum condition for an environment in which appropriate patient-centered care can occur. Therefore, the proposed Governance condition, § 494.180, requires the necessary minimum administrative features to allow the governing body to safely and effectively run a facility in an outcomes environment while being responsive to the patients and to the OIG's recommendation to strengthen the accountability of the governing body.

3. Governance Condition (Proposed § 494.180)

In proposed § 494.180 we state the dialysis facility must be under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The

Medicare program requires that each dialysis facility be independently certified, and therefore, each facility must independently achieve compliance with the conditions for coverage. It is essential that surveyors and networks be able to identify the group or individual with legal responsibility and accountability for managing patient health care, safety, and protection of patient rights and for the operation of each dialysis facility.

4. Designating of a Chief Executive Officer or Administrator (Proposed § 494.180(a))

Proposed § 494.180(a) retains the existing requirement for the governing body or responsible party(ies) to appoint an individual who will serve as the facility's CEO or administrator. We are proposing to use these terms interchangably (that is, CEO and administrator) because the duties would be the same regardless of the title assigned. We have previously proposed that the facility's medical director (*see* § 494.150) assume certain clinical responsibilities for the care provided within the unit. We recognize that in smaller units it would be possible for the same individual to perform the duties of both medical director and CEO/administrator and these regulations do not preclude that. However, in a typical unit we believe the volume, scope, and complexity of administrative, financial, and operational responsibilities requires the day-to-day attention of a separate CEO/administrator position. Therefore, we are proposing to retain this position and the performance of certain duties and responsibilities by the occupant of this position in these proposed conditions.

We are proposing in § 494.180(a) that the CEO/administrator exercise overall management responsibility for the facility and oversee staff appointments, fiscal operations, the relationship with the ESRD network, and the allocation of necessary staff and other resources for the facility's QAPI program (*see* § 494.110).

5. Adequate Number of Qualified and Trained Staff (§ 494.180(b))

Proposed § 494.180(b) would retain and consolidate some of the existing requirements at §§ 405.2136(c)(3)(viii) and 405.2162(b)(2).

We propose at § 494.180(b)(1) to retain the existing requirement at § 405.2162(b)(2) that a dialysis facility ensure an adequate number of qualified personnel are present whenever patients are undergoing dialysis. Under the existing requirement, every approved dialysis facility must maintain staff-to-patient ratios that are appropriate to the level of dialysis care being given in order to meet the needs of its patients. The determination and allocation of appropriate staff-to-patient ratios is left to each dialysis facility. State agency surveyors would assess facility compliance with this requirement by evaluating whether routine care is being delivered, assessments are conducted as the patient's condition changes, routine monitoring adheres to facility policy, and patients care provided by staff during surveys (for example, equipment alarms are responded to promptly). In our deliberations regarding ''adequate staff'', we noted that there is no national consensus within the dialysis industry regarding the appropriate staff-to-patient ratios. We also noted the wide variety of State staff-to-patient ratio requirements. For example, some States have staff-to-patient ratio requirements for registered nurses. Connecticut requires that 50 percent of a dialysis unit's patient care staff be registered nurses. New Jersey requires a registered nurse for the first nine patients in the unit. Georgia and South Carolina mandate a registered nurse for every 10 patients, while Texas requires a registered nurse for every 12 patients. Washington requires two registered nurses per shift. Oregon requires that a written staff plan for registered nurses be on file with the State.

Some States have staff-to-patient ratios for patient care technicians. Maryland, Massachusetts, New Jersey, Washington, Puerto Rico, and the Virgin Islands require a three-to-one patient-to-staff care technician ratio. Georgia, South Carolina, and Texas require a four-to-one patient-to-patient care technician ratio. Nevada has a 100 to 1 patient-to-staff ratio for social workers and renal dietitians. Further complicating the wide variation in State regulations are decisions involving scope of practice and the various nurse practice acts administered by the State boards of nursing. For the reasons cited above, we are not proposing any Federal staff-to-patient ratios.

However, we are interested in strengthening the existing requirement while at the same time preserving the facility's flexibility in determining the appropriate staff-to-patient ratio.

One alternative to mandated staff-to-patient ratios is an acuity-based staffing system developed by each dialysis facility. This type of system would take into account the number of patients treated on each shift, individual patient characteristics, patient needs, the expertise and experience levels of facility staff, the physical layout of the facility, available technology, and the availability of support services. An acuity-based staffing plan, including some or all of the criteria listed above, could be developed by the nurse responsible for nursing services in the facility and approved by the medical director. It could also be incorporated into the facility's QAPI program (*see* § 494.110) as a means of achieving desired outcomes of care specified in the facility's individual patient plans of care (*see* § 494.90). We are soliciting public comment on whether we should include a requirement for an acuity-based staffing plan in § 494.180(b)(1) to ensure that every dialysis facility has ''adequate staffing'' and appropriate staff-to-patient ratios to meet the needs of its patients.

We are proposing in § 494.180(b)(2) that a registered nurse must be present in the facility at all times that patients are being treated. We have made this proposal for several reasons. As previously discussed in this preamble, the rapidly changing demographics of the dialysis patient population has resulted in an older, sicker patient population. An older patient population with more serious co-morbid conditions elevates the potential for medical emergencies (for example, heart attack, stroke, severe reactions to chemicals). A registered nurse has the professional training and expertise to properly react to these types of emergencies. Properly trained dialysis technicians and licensed practical nurses may be effective in providing day-to-day patient care, but may lack the training and expertise to react to critical medical emergencies. Therefore, we believe that having a registered nurse on the premises when treatment is being provided is a necessary health and safety measure for dialysis patients. Registered nurses, by training and professional expertise, are also needed to provide other important patient care functions that occur routinely while patients are being dialyzed. Those functions include: (1) Assessing patient needs; (2) developing treatment plans; (3) coordinating ongoing care in the unit; (4) continually evaluating the ability of the other nursing and technical staff to use the most current skills and techniques; (5) answering clinical questions from patients and staff; (6) and providing direct supervision for dialysis technicians during their 3-month training period (*see* proposed § 494.140(e)(3)).

At § 494.180(b)(3), we are proposing to retain the existing requirement that all employees have appropriate orientation to the facility and their work responsibilities upon employment. In addition, at § 494.180(b)(4), we are

proposing to retain the existing requirement that all employees have an opportunity for continuing education and related development activities.

At § 494.180(b)(5), we are proposing a new requirement for a written approved training program, designed by the facilities, that is specific to dialysis technicians. As discussed earlier in this preamble, dialysis technicians are now the primary caregivers in many dialysis units, and we have proposed minimum Federal requirements for this occupation because we believe properly trained dialysis technicians are essential in achieving good patient outcomes of care (*see* § 494.140(e)). Many States that regulate dialysis technicians require training programs that include: (1) The initiation of dialysis; (2) monitoring and termination of dialysis; (3) possible complications of dialysis; (4) water treatment; and (5) infection control procedures.

We are proposing that every dialysis patient care technician-training program contain criteria that would provide at least a minimal set of skills. When State requirements meet or exceed these proposed patient care technician-training requirements, the State requirements would have to be met. The criteria we are proposing include the following competencies: (1) Principles of dialysis; (2) care of the patient with kidney failure, including interpersonal skills; (3) dialysis procedures and documentation, including initiation, monitoring, and termination of dialysis; (4) possible complications of dialysis; (5) water treatment; (6) infection control; (7) safety; and (8) dialyzer reprocessing, if applicable. We invite public comment on the basic criteria proposed for § 494.180(b)(5)(i) through (viii).

6. Medical Staff Appointments (Proposed § 494.180(c))

In § 494.180(c) we propose to retain some of the existing requirements at § 405.2136(h) that the governing body be responsible to oversee appointments to medical staff. We propose to expand this requirement to include all medical staff appointments, including appointments and credentialing for attending physicians, physician assistants, and nurse practitioners. However, consistent with our goal to reduce unnecessary process-oriented requirements and regulatory burden, we are not proposing to retain the existing requirement in § 405.2136(h) for the governing body to establish written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff (if the facility has a medical staff). Consistent with the new patient outcomes in this regulation, we are proposing to add a new requirement at § 494.180(c)(2) that the governing body be responsible for ensuring that all attending physicians, physicians assistants, and nurse practitioners who provide care in the facility are informed regarding all patient care policies and procedures as well as the QAPI program. We believe adding this new requirement will assist the facility medical director in achieving better patient outcomes through direct care and through the QAPI program without adding any unnecessary burden to a dialysis facility. We are soliciting comments on our proposal to delete process requirements for medical staff appointments and add a new governing body requirement to inform the facility's medical staff regarding the facility's patient care policies and the facility's quality assurance and performance improvement program.

7. Furnishing Services (Proposed § 494.180(d))

Proposed § 494.180(d) would retain the existing requirement § 405.2102 for the governing body to ensure that (except for home care services provided pursuant to § 494.100) services are furnished directly (*see* § 494.10) on its main premises or on other premises that are contiguous with the main premises under the direction of the same professional staff and governing body as the main premises. We believe this requirement is essential to ensure that dialysis services are not provided in uncertified locations.

8. Internal Grievance Process (Proposed § 494.180(e))

In § 494.180(e), we are proposing to require that facilities have an internal grievance process. We believe a good internal grievance process is an invaluable tool in resolving patient grievances in a positive and expeditious manner for both the patient and the facility. The grievance process must include a clearly explained procedure for the submission of grievances, timeframes for reviewing the grievance, and a description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance. The grievance process must be implemented so that the patient may file a grievance with the facility without reprisal or denial of services.

9. Discharge and Transfer Policies and Procedures (Proposed § 494.180(f))

We are also proposing that the facility's discharge and transfer policy be designed to ensure that no patient, including disruptive or noncompliant patients, is discharged or transferred from the facility unless one of the following situations applies:

- The patient or payor will no longer reimburse the facility for covered services;
- The facility ceases to operate;
- The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs;
- The facility has determined the patient's behavior is so disruptive or abusive that the facility is unable to deliver care to the patient or to operate effectively.

We are proposing that the governing body assign the medical director the responsibility to monitor and review every patient discharge of an abusive or disruptive patient to ensure that the patient's interdisciplinary team has reassessed the patient and documented the ongoing problem(s) and efforts to resolve the problem(s); obtained a written physician's order which must be signed by the medical director and (if applicable) the patient's attending physician; and that a documented attempt has been made to place the patient in another facility. The State survey agency and the ESRD network must be notified of the involuntary discharge of any patient. We believe, as the individual in charge of patient care in the facility, the medical director (*see* proposed § 494.150(c)(2)(ii)) is the appropriate individual to ensure that a patient's interdisciplinary team has followed the procedure described in § 494.180(f) before any transfers or discharges from the facility. We also believe it is important to allow facilities the flexibility to make these determinations on a case-by-case basis without the imposition of prescriptive criteria that would define disruptive or abusive behavior. However, the facility's interventions and reasons for involuntary discharge of a disruptive or abusive patient must be clearly documented in the patient's medical record. We invite comments on our proposal to hold the dialysis facility accountable for their staff adherence to facility's patient discharge or transfer policies and procedures.

10. Emergency Coverage (Proposed § 494.180(g)

Proposed § 494.180(g) would require the governing body to be responsible for emergency coverage. Emergency coverage is not the same thing as emergency preparedness (*see* § 494.60(d) in the proposed physical environment condition). As previously

discussed, emergency preparedness applies to medical and nonmedical emergencies related to fire, equipment or power failures, care-related emergencies, water supply interruptions, and natural disasters. The emphasis in emergency preparedness is on the facility staff's ability to manage and respond appropriately to these facility-wide problems. Emergency coverage, as proposed in § 494.180(g), relates only to patient medical emergencies. Specifically, proposed § 494.180(g)(1) would require the governing body to ensure that patients and staff have written instructions for obtaining emergency medical care. We believe giving patients and staff written instructions is both prudent and necessary to ensure that every patient has the necessary information if and when a medical emergency should arise.

Proposed § 494.180(g)(2) would retain the existing provision at § 405.2136(g)(2) that requires the dialysis facility to post, at the nursing/monitoring station, a roster of physician names to be called for emergencies, when they can be reached, and how they can be reached.

Proposed § 494.180(g)(3) retains and combines existing provision at § 405.2136(g)(2) which requires the governing body to ensure emergency care is always available, and existing § 405.2160 which requires the facility to have an agreement with a hospital to provide inpatient care and other services to patients at all times. However, our proposed agreement requirement at § 494.180(g)(3) is much less prescriptive than the existing requirement at § 405.2160, which is a condition-level requirement. For example, § 405.2160 requires a dialysis facility to have an agreement with a renal dialysis center, which is defined in existing § 405.2102 as a hospital that is qualified to provide the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients. Existing § 405.2160 also contains explicit requirements for the affiliation agreement, that is, the agreement must (1) include the basis for working relationships between staff of both facilities to ensure that services are available promptly; (2) specify transfers for only medically appropriate circumstances as determined by the medical director or attending physician; (3) prescribe an interchange (within 1 working day) between facilities of the patient's long-term plan and patient care plans; and (4) specify security and accountability for patients' personal effects. Our proposal, at § 494.180(g)(3) states simply that the dialysis facility must have an arrangement with a hospital that can provide inpatient care, other hospital services, and emergency services which are available 24 hours a day, 7 days a week; services will be made available promptly; and there are reasonable assurances in the agreement that patients from the dialysis facility will be accepted and treated in emergencies. This is consistent with our goal of transitioning from unnecessary procedural and process requirements to a patient-outcomes environment in which a dialysis facility will have more flexibility in determining how necessary services, including emergency services, are provided to its patients.

11. Furnishing Data and Information for ESRD Program Administration (Proposed § 494.180(h)

We propose in § 494.180(h) that dialysis facilities furnish data and information electronically and in intervals that conform to specifications established by the Secretary. While reporting data and information is an existing requirement in § 405.2133, the proposal to require the ESRD CPM data and to require electronic data reporting are new requirements. The CPM project, a quality improvement initiative between CMS, the ESRD networks, and ESRD facilities was discussed in section II.E.4.1 of this proposed rule. Currently, dialysis facilities participate in this project voluntarily. We are proposing full participation in reporting the existing CPMs by all dialysis facilities. We have received recommendations from the OIG ''External Quality Review of Dialysis Facilities/A Call For Greater Accountability,'' the IOM ''Crossing the Quality Chasm, 2001'', and Medicare Payment Advisory Commission (MedPAC) ''Improving Quality Assurance for Institutional Providers'' to require facilities participating in Medicare to report on performance measures to stimulate improvements in the quality of care and to achieve a degree of accountability for performance ((DHHS/OIG, 1999), (IOM, 2001), and (MedPAC, 2000) respectively). The requirement for full CPM reporting is an important step in moving in that direction.

Section 4558(b) of Pub. L. 105–33 requires us to develop a method to measure and report the quality of dialysis services provided in the Medicare program. To comply with this requirement, we developed the CPMs from the NKF–DOQI (now NKF–K/DOQI) clinical practice guidelines. The CPM project assists providers in the assessment of care provided to ESRD patients and stimulates improvement in that care. The processes used to develop the CPMs and the DOQI guidelines were also discussed in section II.E.3 and 4 of this preamble.

Dialysis facilities and ESRD networks have used the ESRD CPM project annual reports for benchmarking purposes and as a means of identifying opportunities to improve care. The approach of this proposed rule is to decrease process requirements and instead look to outcomes of patient care so that quality may be assessed and reported. The CPMs will be a part of the vehicle by which we measure and report on the quality of dialysis services provided in the Medicare program.

The CPM data collection tools were briefly described in section II.E.5 of this preamble. Data elements included on these forms are intermediate outcome measures and process markers for adequacy of hemodialysis and peritoneal dialysis, anemia management, nutrition (albumin), and vascular access management.

The CMS VISION software will provide the electronic means for collection of the ESRD administrative forms (that is, CMS–2728, CMS–2746, and CMS–2744) as well as the CPM data (CMS–820 and CMS–821). In the future, CMS VISION software may also collect other information such as patient experience of care survey data. The VISION program will utilize an encryption technology that assures privacy, confidentiality, and security for electronic communications. The requirement for full CPM reporting on all patients by all facilities will be implemented only when the VISION software is fully operational. Vision software will be provided to independent dialysis facilities and small to medium size corporate dialysis facilities at no cost. Specifications are being provided for developing an interface between the major corporate dialysis facilities' databases and the CMS database to enable ESRD administrative data and CPM data to be transmitted electronically with minimal effort from dialysis facility staff. There are initial costs for major corporate dialysis facilities as they develop the software interface and for initial training. For a more detailed discussion of these costs see section IX. of this preamble.

The Secretary will determine the frequency of CPM data collection. Facilities currently report (via billing submissions) monthly URR values for all hemodialysis patients and monthly hematocrit levels for all patients receiving erythropoietin.

The CPM data collection would provide a means for the reporting of facility-specific performance measures capturing information related to the

quality of care delivered. This kind of information is especially important if a fully-bundled payment system for the ESRD program expands the composite rate structure to include all outpatient routine dialysis payments. We are concerned that this change in the payment structure could provide financial incentives to reduce services provided to ESRD beneficiaries; thereby compromising quality of care. Any shift in payment policy necessitates a strong external monitoring process to ensure that an acceptable level of care continues. The reporting of facility-specific performance measures and the development of standards would provide us with the means externally to evaluate and monitor dialysis facilities to ensure that the necessary services have been provided and to assist patients to reach optimal outcomes.

We are looking at the feasibility of developing minimum performance standards. There are widely accepted (K/DOQI) clinical practice guidelines and clinical performance measures (CPMs) in existence. However, there is no consensus for minimum performance standards. Dialysis facility performance is generally compared to performance of other facilities in the network or to national performance data. Facilities whose performance measures fall well below the comparison group are generally identified as needing improvement. However, we do not have defined thresholds that tell us, for example, that if a dialysis facility provided a KT/V of 1.2 or higher to at least 85 percent of its hemodialysis patients, that facility is providing an acceptable level of care.

An additional problem in using minimum standards for accountability purposes is the possibility of ''cherry picking'' and decreased access to dialysis for some patients. Dialysis facilities may have a disincentive to accept patients likely to be more difficult to manage as well as patients that are more resource-intensive and who are less likely to achieve acceptable levels on the performance measures. This raises the issue of the necessity of risk adjusters to be used in developing the bundled payment rate, as well as developing performance standards for accountability. We are looking at these difficult issues and considering the implications of any changes in payment and performance accountability. We are soliciting comments on how the incentives to ''cherry pick'' could be minimized. Any performance standards that we may use for dialysis facilities would be developed in conjunction with the NTTAA process discussed in section II.E.6 of this preamble.

This proposal, which requires CPM reporting, is specific to the CPMs as they currently exist. The process for updating, revising, and expanding the CPMs will be done in conjunction with the NTTAA process. A voluntary consensus standards body, which as yet has not been identified, would likely plan, develop, establish, or coordinate voluntary consensus standards using agreed upon procedures in conjunction with the NTTAA.

In the February 19, 1998 **Federal Register** (63 FR 8546), the Office of Management and Budget published a notice regarding the Federal participation in the development and use of voluntary consensus standards. We will use the policies established in this publication and the Administrative Procedure Act (APA) when adopting voluntary consensus standards. If we adopt voluntary consensus standards that are not legally binding, we would publish them as a notice in the **Federal Register**.

The ESRD CPM project data, which would provide the use patterns of 100 percent of dialysis patients, would provide an array of possibilities for facilities to compare performance and practice patterns at facility, State, network, and national levels in order to identify opportunities for improvement in the care of dialysis patients.

This information would provide independent dialysis facilities with the same type of information that some dialysis chain corporations have been able to collect on their own dialysis facilities across the nation. These CPM data would expand the breadth of data that have been previously available even to the large dialysis corporations.

The ESRD networks would use the CPM data elements and calculated measures in order to assist dialysis facilities with quality improvement activities and as a benchmark to look at their own performance.

The State survey agencies would receive facility profiles as well as data for dialysis adequacy, vascular access, anemia management, and nutrition for use in their survey activities.

At a minimum, we would use the following facility-specific information for public reporting on our Dialysis Facility Compare Web site:

- Number of patients included in each calculation.
- Percent of patients treated in the facility with a Kt/V $\geq$ 1.2.
- Percent of patients treated in the facility with a hemoglobin $\geq$ 11 gms/dL.

Public reporting of performance measures provides an important resource to dialysis patients and their families. The Dialysis Facility Compare website provides detailed information about Medicare-certified dialysis facilities and allows for comparison of facility characteristics and quality measures. We are evaluating the information reported on the Dialysis Facility Compare website for usability and to ensure that the publicly reported information meets the needs of the beneficiary. The availability of information will permit patients to become more active participants in their facilities' quality improvement process. Informed patients make better health care choices and are more active participants in their medical care.

12. Disclosure of Ownership (Proposed § 494.180(i))

In § 494.180(i) we are proposing to retain the existing § 405.2136(a) that the dialysis facility must provide complete information to the State survey agency regarding persons who have any direct or indirect ownership of the facility in whole or in part in compliance with the requirements of §§ 420.200 through 420.406. This requirement, reporting ownership interests of 5 percent or more, is a conforming change to comport with the existing requirements in § 420.201, which have been in effect since 1992.

VII. Other Proposed Changes and Issues

A. Proposed Cross-Reference Changes

[If you choose to comment on issues in this section please include the caption ''Cross-Reference Changes'' at the beginning of your comment.]

We are proposing to make technical changes in the following sections of the regulations to correct cross-references to the sections in part 405, subpart U that are proposed to be relocated or deleted: §§ 410.5, 410.50, 410.52, 410.152, 410.170, 413.170, 413.172, 413.198, and 414.330.

B. Proposed Additions to Part 488

[If you choose to comment on issues in this section please include the caption ''Part 488'' at the beginning of your comment.]

We are proposing to add a new subpart H to part 488. Proposed subpart H would consist of the existing sanction provisions in part 405 subpart U. The existing sanction provisions are in §§ 405.2180, 405.2181, 405.2182, and 405.2184 and are summarized as follows:

- Section 405.2180 specifies the basic sanction, which is termination of Medicare coverage, and the basis for reinstatement of coverage after termination.
- Section 405.2181 specifies the alternative sanctions denial of payment

of any patients accepted for care after the effective date of the sanction, and gradual reduction of payments for all patients) and the circumstances under which they might be imposed.

• Section 405.2182 specifies the notice procedures that we will follow and the appeal rights of sanctioned suppliers.

• Section 405.2184 specifies (in greater detail) the rights of suppliers that appeal proposed imposition of an alternative sanction.

We propose to redesignate these provisions (with technical and cross-reference changes) as §§ 488.604, 488.606, 488.608, and 488.610 respectively.

VIII. Reference Materials

A. New Provisions of Part 494

This proposed rule contains a number of requirements that are not included in the existing regulations. For information and ease of reference, outlined below is a list of the new provisions, grouped by condition:

Condition	New provisions
Infection control (§ 494.30)	§ 494.30(a)—Infection control procedures (including the Recommended Infection Control Practices for Hemodialysis Units At a Glance CDC guidelines).
	§ 494.30(a)(2)—Patient isolation procedures.
Water quality (§ 494.40)	§ 494.40—Incorporates by reference the updated 2001 American National Standard/Association for the Advancement of Medical Instrumentation guidelines for water purity.
Physical environment (§ 494.60)	§ 494.60(e)—Fire safety.
Patient rights (§ 494.70)	§ 494.70(a)(5)—Advance directives.
	§ 494.70(a)(14)—Complaint systems.
	§ 494.70(b)—Discharge and transfer policies.
	§ 494.70(d)—Posting of rights.
Patient assessment (§ 494.80)	§ 494.80(a)(2)—Appropriateness of dialysis prescription.
	§ 494.80(a)(5)—Renal bone disease.
	§ 494.80(a)(8)—Dialysis access type and maintenance.
	§ 494.80(a)(10)—Suitability for transplantation referral, including basis for referral or non-referral.
	§ 494.80(b)—Frequency of assessment.
	§ 494.80(c)—Assessment of treatment prescription.
	§ 494.80(d)—Patient reassessment.
Patient plan of care (§ 494.90)	§ 494.90(a)(1)—Dose of dialysis.
	§ 494.90(a)(2)—Nutritional status.
	§ 494.90(a)(3)—Anemia.
	§ 494.90(a)(4)—Vascular access.
	§ 494.90(a)(5)—Transplantation status.
	§ 494.90(a)(7)—Rehabilitation status.
	§ 494.90(b)—Implementation of patient plan of care.
	§ 494.90(b)(3)—Direct physician/patient interaction.
	§ 494.90(c)—Transplantation referral tracking.
Care at home (§ 494.100)	§ 494.100(a)—Training.
	§ 494.100(b)—Home dialysis monitoring.
	§ 494.100(c)—Support services.
Quality assessment and performance improvement (§ 494.110).	§ 494.110(a)—Program scope.
	§ 494.110(a)(2)(i)—Adequacy of dialysis.
	§ 494.110(a)(2)(ii)—Nutritional status.
	§ 494.110(a)(2)(iii)—Anemia management.
	§ 494.110(a)(2)(iv)—Vascular access.
	§ 494.110(a)(2)(v)—Medical injuries and medical error identification.
	§ 494.110(a)(2)(vi)—Hemodialyzer reuse.
	§ 494.110(a)(vii)—Patient satisfaction.
	§ 494.110(b)—Monitoring performance improvement.
	§ 494.110(c)—Prioritizing improvement activities.
Special purpose renal dialysis facilities (§ 494.120).	(§ 494.120)—Definition.
Personnel qualifications (§ 494.140)	§ 494.140(b)—Nursing services.
	§ 494.140(e)—Dialysis technicians.
Responsibilities of the medical director (§ 494.150).	§ 494.150(a)—Quality assessment and performance improvement program.
	§ 494.150(b)—Staff education, training, and performance.
	§ 494.150(c)—Patient care policies and procedures.
Governance (§ 494.180)	§ 494.180(c)—Medical staff appointments.
	§ 494.180(d)—Furnishing services.
	§ 494.180(e)—Internal grievance process.
	§ 494.180(f)—Discharge and transfer policies and procedures.
	§ 494.180(g)—Emergency coverage.
	§ 494.180(h)—Furnishing data and information for ESRD program administration.

B. ESRD Crosswalk (Cross Refers Existing Requirements to Proposed Requirements)

Existing conditions (part 405, subpart U)	Existing citation	Proposed conditions (part 494)	Proposed citation
Scope of subpart	405.2100(a)	Basis and scope	494.1
	405.2100(b)	Deleted.	
Objectives of ESRD program	405.2101	Deleted.	
Definitions	405.2102	Definitions	494.10
Agreement		Deleted	
Arrangement		Deleted	
Dialysis		Deleted	
End-stage renal disease		Deleted	406.13(b)
ESRD facility (introductory text)			
(a) Renal transplantation center		Retained in 405, Subpart U	494.10
(b) Renal dialysis center		Deleted	
(c) Renal dialysis facility		Definitions	494.10
(d) Self-dialysis unit		Deleted	
(e) Special purpose renal dialysis facility		Special purpose renal dialysis facilities.	494.120
ESRD service (introductory text)		Retained in 405, Subpart U	
(a) Transplantation service		Deleted	
(b) Dialysis service		Deleted	
(1) Inpatient dialysis		Deleted	
(2) Outpatient dialysis		Deleted	
(i) Staff-assisted dialysis		Definitions	
(ii) Self-dialysis		Deleted	494.10
(3) Home dialysis		Care at home	
(c) Self-dialysis and home dialysis		Deleted	494.100
Furnishes directly		Governance	
Furnishes on the premises		Retained in 405, Subpart U	494.180(d)
Histocompatibility testing		Deleted	
Medical care criteria		Deleted	
Medical care norms		Deleted	
Medical care standards		Deleted	
Medical care evaluation study		Deleted	
Network ESRD		Retained in 405, Subpart U	
Network organization		Retained in 405, Subpart U	
Organ procurement (introductory text)		Deleted	
		Governance	
(a) Chief executive officer		Personnel qualifications	494.190(a)
(b) Dietitian		Deleted	494.150(c)
(c) Medical record practitioner		Personnel qualifications	
(d) Nurse responsible for nursing services		Personnel qualifications	494.150(b)
(e) Physician-director		Personnel qualifications	494.150(a)
(f) Social worker		Retained in 405, Subpart U	494.150(d)
(g) Transplantation surgeon			
Designation of ESRD networks	405.2110	Retained in 405, Subpart U	
[Reserved]	405.2111	Deleted	
ESRD network organizations	405.2112	Retained in 405, Subpart U	
Medical review board	405.2113	Retained in 405, Subpart U	
[Reserved]	405.2114	Deleted	
Minimum utilization rates: General	405.2120	Retained in Subpart U	
Basis for determining minimum utilization rates	405.2121	Retained in Subpart U	
Types and duration of classification according to utilization rates.	405.2122	Retained in Subpart U	
Reporting of utilization rates for classification	405.2123	Retained in Subpart U	
Calculation of utilization rates for comparison with minimum utilization rate(s) and notification of status.	405.2124	Retained in Subpart U	
Minimum utilization rates	405.2130	Retained in Subpart U	
Provider status: renal transplantation center or renal dialysis center.	405.2131	Retained in 405, Subpart U	
[Reserved]	405.2132	Deleted	
Furnishing data and information for ESRD program administration.	405.2133	Governance	494.190(f)
Participation in network activities	405.2134	Relationship with ESRD network.	494.170
Compliance with Federal, State, and local laws and regulations.	405.2135	Compliance with Federal, State, and local laws and regulations.	494.20
Governing body and management	405.2136	Governance	494.180 (introductory text)
(a) Disclosure of ownership	405.2136(a)	Governance	494.180(g)
(b) Operational objectives	405.2136(b)	Deleted	
(c) Chief executive officer	405.2136(c)	Governance	494.180(a)
(d) Personnel policies and procedures	405.2136(d)(1,3–5,7)	Deleted	
(d)(2) Infection control/Incident reports	405.2136(d)(2)	Infection control and Quality assessment and performance improvement.	494.30(a) & 494.110(a)(5)

Existing conditions (part 405, subpart U)	Existing citation	Proposed conditions (part 494)	Proposed citation
(d)(6) Facility personnel educational programs	405.2136(d)(6)	Personnel qualifications	494.140(e)
(e) Use of outside resources		Medical Director	494.150(c)
(f) Patient care policies	405.2136(e)	Deleted	
(g) Medical supervision and emergency coverage	405.2136(f)	Medical Director	494.150(d)
	405.2136(g)(1)	Patient plan of care	494.90 (introductory text)
(h) Medical staff		Care at home and Governance.	494.100(c) & 494.180(b)
	494.2136(g)(2)	Governance	494.180(e)
	405.2136(h)	Governance	494.180(c)
Patient long-term program and patient care plan	405.2137 (introductory text).	Patient care plan	494.90 (introductory text)
(a) Patient long-term program	405.2137(a)	Deleted	
(b) Patient care plan	405.2137(b)	Patient care plan	494.90 (introductory text)
(b)(1) Personalized care plan	405.2137(b)(1)	Patient care plan	494.90 (introductory text)
(b)(2) Developed by a professional team	405.2137(b)(2)	Patient care plan	494.90 (introductory text)
(b)(3) The patient is involved	405.2137(b)(3)	Patient rights	494.70(a)(5)
(b)(4) Frequency of care plan review	405.2137(b)(4)	Patient plan of care	494.90(b), (1)
(b)(5) Transfer of care plan	405.2137(b)(5)	Medical records	494.170(d)
(b)(6) Care plan for the home dialysis patient	405.2137(b)(6)	Care at home	494.100 (introductory text)
(b)(7) Erythropoietin for the home dialysis patient	405.2137(b)(7)	Patient plan of care	494.90(a)(3)
Patient's rights and responsibilities	405.2138(a)–(d)	Patient rights and medical records.	494.70(a) and 494.170(a)
	405.2138(e)	Patient rights	494.70(c) (13 and 14)
Medical records	405.2139	Recordkeeping	494.170 (introductory text)
(a) Medical record contents	405.2139(a)	Deleted	
(b) Protection of medical record information	405.2139(b)	Recordkeeping	494.170(a)
(c) Medical record supervisor	405.2139(c)	Deleted	
(d) Completion and centralization	405.2139(d)	Recordkeeping	494.170(b)
(e) Retention and preservation	405.2139(e)	Recordkeeping	494.170(c)
(f) Location and facilities	405.2139(f)	Deleted	
(g) Transfer of medical information	405.2139(g)	Recordkeeping	494.170(d)
Physical environment	405.2140(a) (introductory text).	Physical environment	494.60 (introductory text)
(a) Building and equipment	405.2140(a)(1)		
(a)(1) Fire	405.2140(a)(2), (3)	Physical environment	494.60(e)
(a)(2), (3) Equipment and areas are hazard free		Physical environment	494.60(a), (b)
(a)(5) Water quality requirements	405.2140(a)(5)		
(b) Favorable environment for patients	405.2140(b) (introductory text).	Water quality	494.40
(b)(1) Infection prevention		Physical environment	494.60(c)
(b)(2)(4) Adequate treatment areas/Heating and ventilation systems.	405.2140(b)(1)	Infection control	494.60(c)
	405.2140(b)(2)(4)	Physical environment	494.60(c)
(b)(3) Nursing station			
(b)(5) Special dialysis solutions	405.2140(b)(3)	Deleted	
(c) Contamination prevention	405.2140(b)(5)	Deleted	
	405.2140(c)	Infection control and Reuse of.	494.30(a) and 494.40
(d) Emergency preparedness	405.2140(d)	Hemodialyzers	(introductory text), (a)
		Physical environment	494.60(d)
Reuse of hemodialyzers and other dialysis supplies	405.2150 (introductory text).	Reuse of hemodialyzers and Bloodlines.	494.50 (introduction)
(a) Hemodialyzers	405.2150(a)(1–3)	Reuse of hemodialyzers and Bloodlines.	494.50 (introduction), (a), (b)
(b) Transducer filters	405.2150(b)	Infection Control	494.30(a)(1)
(c) Bloodlines	405.2150(c)	Resuse of hemodialyzers and Bloodlines.	494.50(c)
Affiliation agreement or arrangement	405.2160 (a), (b)(1), (b)(3)	Governance	494.180(e)(3)
	405.2160(b)(2)	Medical records	494.170(d)
Director of a renal dialysis facility or renal dialysis center.	405.2161	Personnel qualifications	494.140(a)
		Medical Director	494.150
Staff of a renal dialysis facility or renal dialysis center	405.2162 (stem statement)	Governance	494.180(b)
Adequate numbers of personnel are present to meet patient needs.	405.2162(a)	Governance	494.180(b)
(a) Registered nurse	405.2162(b)	Personnel qualifications	494.140(b) & (e)
(b) On-duty personnel	405.2162(b)	Governance	494.180(b)
(c) Self-care dialysis training personnel	405.2162(c)	Care at home	494.100(a)
Minimal service requirements for a renal dialysis facility or renal dialysis center.	405.2163	Patient plan of care	494.90 (introductory text)
(a) Outpatient dialysis services	405.2163(a)	Patient plan of care	494.90
		Care at home	494.100
(b) Laboratory services	405.2163(b)	Laboratory services	494.130
(c) Social services	405.2163(c)	Patient Assessment	494.80(a)

Existing conditions (part 405, subpart U)	Existing citation	Proposed conditions (part 494)	Proposed citation
		Patient plan of care	494.90(a)
		Care at home	494.100(a)
(d) Dietetic services	405.2163(d)	Patient Assessment	494.80(a)
		Patient plan of care	494.90
(e) Self-dialysis support services	405.2163(e)	Care at home	494.100(c)
(f) Participation in recipient registry	405.2163(f)	Patient plan of care	494.90(c)
(g) Use of erythropoietin at home	405.2163(g)	Patient Assessment	494.80(a)(4)
		Patient plan of care	494.90(a)(3)
		Care at home	494.100(a)(2)
(h) Responsibilities of the physician/facility for use of erythropoietin at home.	405.2163(h)	Care at home	494.100(b)(2)
Conditions for coverage of special purpose renal dialysis facilities.	405.2164	Special purpose renal dialysis facilities.	494.120
Director of a renal transplantation center	405.2170	Retained in 405, Subpart U	
Minimal service requirements for a transplantation center.	405.2171 (introductory text).	Retained in 405, Subpart U.	
	405.2171(a)–(e)		
Termination of Medicare coverage	405.2180	Termination of Medicare coverage.	488.604
Alternative sanctions	405.2181	Alternative sanctions	488.606
Notice of sanction and appear rights: Termination of coverage.	405.2182	Notice of appeal rights: Termination of coverage.	488.608
Notice of appeal rights: Alternative sanctions	405.2184	Notice of appeal rights: Alternative sanctions.	488.610

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VIII. Collection of Information Requirements and Response to Comments

A. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 414.330 Payment for home dialysis equipment, supplies and support services. Suppliers must report to the ESRD facility providing support services, every 30 days, all data for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Section 488.60 Special procedures for approving end stage renal disease facilities. An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494, must submit the documents and data as outlined in § 488.60(a)(1) through (a)(4).

We estimate that it will take 250 facilities on an annual basis 40 hours each to gather and submit the necessary documentation for consideration of approval.

Section 494.30 Condition: Infection control. The dialysis facility must maintain current infection control information including the most current CDC guidelines for the proper techniques in the use of vials and ampules containing medication. In addition, facilities must report infection control issues to the dialysis facility's chief executive officer or administrator (*see* § 494.180(a)) and the quality improvement committee.

While these requirements are subject to the PRA, the fact that they are usual and customary business practices, exempts the burden associated with these requirements from the PRA as stipulated under 5 CFR 1320.3(b)(2).

The facility must document the incidence of infection to identify trends and establish baseline information on infection incidence, develop recommendations to prevent infection transmission and take corrective actions to reduce future incidents, and report incidences of communicable diseases as required by Federal, State and local laws.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.40 Condition: Water quality. If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine described at § 494.30(c)(2)(i) the facility must immediately notify the medical director.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Section 494.50 Condition: Reuse of hemodialyzers and bloodlines. The dialysis facility must monitor patient reactions, undertake evaluation of its dialyzer reprocessing and water purification system, and report any adverse outcomes to FDA and other Federal, State, or local governments agencies as required by law.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and is required under other Federal, State, and local laws, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.70 Condition: Patients' rights. The dialysis facility must inform patients (or their representatives) of their rights and responsibilities when they begin their treatment. The facility must also inform patients of the facility's policies for transfer, discharge, and discontinuation of services to patients.

We estimate that 4,317 facilities will need 8 hours each on an annual basis to disclose the necessary information. This is based on the belief that the materials will be standardized and incorporated into the facility's entrance materials.

In addition, the dialysis facility must prominently display a copy of the patients' rights in the facility. These rights must include the current State agency and ESRD network telephone compliant numbers and it must be posted in a place where it can be easily seen and read by patients.

We estimate that 4,317 facilities will need 1 hour each on an annual basis to comply with this requirement.

Section 494.90 Condition: Patient plan of care. The interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that meets the requirements of § 494.90.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.100 Condition: Care at home. The dialysis facility must document in the patient's medical record, that the patient, the caregiver, or both received and comprehended required training. In addition, the facility must document, in the patient's medical record, that the self-monitoring data and other information from self-care were reviewed, at least every 2 months.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.110 Condition: Quality assessment and performance improvement. The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven interdisciplinary quality assessment and performance improvement program that reflects the complexity of the dialysis facility's organization and services.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.120 Condition: Special purpose renal dialysis facilities. Facilities must contact the patient's physician prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the plan of care (specified in § 494.90).

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Facilities must document all care provided in the special purpose facility and forward the documentation to the patient's dialysis facility within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.170 Condition: Medical records. The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

The dialysis facility must obtain written authorization from the patient or legal representative before releasing information that is not compelled by law.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Patient records must be retained for a period of time not less than that required by State law, or in the absence of State law, 5 years from the date of discharge, including death for adults and 3 years for minors or until the patient reaches legal age under State law, whichever is longer.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

When a dialysis patient is transferred, the transferring facility must provide the receiving facility with all medical records and other information necessary or useful in the patient's care or treatment.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.180 Condition: Governance. The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

The dialysis facility must have a written agreement, that meets the requirements in § 494.180, with a hospital that can provide inpatient care, other hospital services, and emergency medical care that is available 24 hours a day, 7 days a week.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

The facility must provide each patient with written notice 30 days in advance of the facility reducing or terminating ongoing care after following the procedure specified in § 494.180(f).

We estimate that 500 facilities will need 1 hour on an annual basis to provide the required disclosure. This is

based on the assumption that the disclosure will be standardized and will not be required by the majority of facilities.

The dialysis facility must furnish data information electronically to CMS at intervals specified by the Secretary, which meet the requirements referenced in this section.

While these requirements are subject to the PRA, they are currently approved under the following OMB approval numbers: 0938–0046, 0938–0360, 0938–0386, 0938–0657, and 0938–0658.

In accordance with §§ 420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

While these requirements are subject to the PRA, it is currently approved under OMB approval number 0938–0086.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in §§ 414.330, 488.60, 494.40, 494.50, 494.70, 494.80, 494.90, 494.100, 494.110, 494.120, 494.170, and 494.180. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Dawn Willinghan, Room C4–26–05, 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: Christopher J. Martin, CMS Desk Officer, *Christopher_J._Martin@omb.eop.gov.* Fax: (202) 395–6974.

B. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

X. Regulatory Impact Analysis

[If you choose to comment on issues in this section please include the caption ''Impact Analysis'' at the beginning of your comment.]

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is a proposed revision of the Medicare conditions for coverage for end-stage renal disease (ESRD) facilities. The conditions for coverage are the basic health and safety requirements that an ESRD supplier of services must meet in order to receive payment from the Medicare program. This proposed rule would incorporate new scientific advances and current medical practices in treating ESRD while removing numerous burdensome process and procedural requirements contained in the existing conditions for coverage. While it is not possible at this point to determine definitively the additional costs to the Medicare program resulting from this rule, we believe that the impact will be below the $100 million threshold; and therefore, believe that this proposed rule is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Individuals and States are not included in the definition of small entity. According to the latest numbers from the Small Business Administration's North American Industrial Classification System, 37 percent (1,751) of dialysis facilities have revenues of $29 million or less annually; and therefore, are considered to be small entities. Thirty of these facilities have annual revenue less than $100,000. It is possible that this proposed regulation could cost some of these small facilities an additional $6,545 (about 6.5 percent of $100,000). However, this is an essential upgrading necessary to bring these facilities into conformity with what is becoming standard practice in the renal field and to provide essential quality in health care, potentially saving lives. For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural facilities.

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. Since this rule applies only to dialysis facilities, it has no impact on small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule has no impact on the expenditures of State, local or tribal governments, and the impact on the private sector is estimated to be less than $110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have any effect on State and local governments. The costs associated with treating ESRD are currently a Medicare-covered benefit for individuals with ESRD. This rule will not increase the costs of the Medicare program.

B. Impact of the Proposed Policy Changes

1. Retained Requirements

We note that we have retained a number of requirements from the existing regulations in this proposed rule. Therefore, these requirements do not add any new financial burden for dialysis facilities. These requirements include the following:

- Special procedures for approving end stage renal disease facilities.
- Infection control.
- Water quality.
- Reuse of hemodialyzers.
- Patient plan of care.

2. Physical Environment and Emergency Preparedness

The existing regulations require dialysis facilities to have written policies and procedures for handling emergencies with annual reviews, testing, and revisions, and staff training to handle any emergency or disaster. Facilities are now expending resources to develop procedures and train staff for natural disasters that had never been known to occur in their region. The proposed rule requires only that the staff be able to demonstrate the ability to manage emergencies that are likely to occur in the facility's geographic area. Although an annual review would still be required, the proposed rule does not require the involvement of the CEO in this activity. We estimate a typical facility will expend 4 hours less of staff time for this activity at $50 per hour, with a net savings of $200 per year for an overall savings of $947,000.

The proposed rule requires that the facility meet the 2000 edition of Life Safety Code (LSC) requirements of the National Fire Protection Association. Most dialysis facilities currently meet most of the provisions required in Chapter 21 of the LSC because of State and local building codes as well as facilities' own liability purposes. However, there may be some burden for existing facilities in regard to the installation and maintenance of the fire department alarm connection. We estimate that approximately 1,136 facilities will need to be upgraded to meet this requirement. The one-time cost to install a fire department or central monitoring station connection is estimated to be $1,000 per facility. The monthly fee for the monitoring station and telephone cost is estimated to be about $80. Thus, we estimate the additional overall cost of compliance for facilities in the first year will be $2,226,500, with the annual cost thereafter being $1,090,560 ($80 month X 12 months X 1,136 facilities).

This estimate does not take into account any specific waivers or acceptance of a State code in lieu of the LSC that may decrease the burden. If the health and safety of patients and staff are not adversely affected, the proposed rule would permit us to waive specific provisions of the LSC, which, if rigidly applied, would result in an unreasonable hardship on the facility. In addition, the proposed rule specifies that the Secretary, may accept a State code in lieu of the LSC, if it adequately protects patients.

The proposed rule requires that every dialysis facility have access to a defibrillator. As discussed earlier in this preamble, USRDS data on causes of death among hemodialysis patients between 1997 and 1999 indicates that nearly half (49 percent) of the deaths were attributable to cardiovascular conditions, with cardiac arrest ranking first among the specified causes.

One study found that the typical dialysis facility faces one cardiac arrest each year (Becker, pp. 1509–1512). The study estimated the cost of AEDs at $3,000, with a useful life of 10 years, that is, $300 annually for each life potentially saved. Currently, AEDs can be purchased for $2,000 with a useful life of 10 years (that is, an AED can be use at a cost of $200 each year for 10 years).

Since 19 percent of dialysis facilities are hospital-based, it is presumed that these facilities have already met the requirement, since they have access to an in-hospital defibrillator. However, we assume that all of the remaining 81 percent of facilities would have to acquire this piece of equipment. The only ongoing annual costs for maintaining the equipment are those for testing and replacing batteries, and these costs are negligible. The cost of AEDs in 81 percent of dialysis facilities is estimated to be $7,670,700. We have requested public comment regarding the AED proposal as well as comments regarding the appropriateness of waivers or a phase-in period or both for small rural dialysis facilities.

3. Patients' Rights

The existing regulations require dialysis facilities to have written patients' rights policies and procedures and a list of numerous persons to whom the patient rights policies must be made available. The proposed rule details basic information that must be provided to patients (for example, advance directives and how to contact entities in regard to complaints) but only requires that patient rights be prominently displayed. Proposing minimum contents in the patients' rights condition, and proposing only that these rights be posted, will limit the administrative burden. We estimate that this will save the typical facility about 2 hours of staff time at $15 per hour, that is, $30 annually, for an overall savings of $142,050.

The existing regulations require translators when a significant number of patients exhibit language barriers. The proposed rule would delete this requirement and specify information be given to patients in a manner that assures their understanding. However, translators could still be used and facilities would have more flexibility in overcoming language barriers in lieu of hiring translators. This results in a net reduction in facility costs.

The existing regulations require that advance notice be given to patients who are being terminated from a dialysis facility. The proposed rule is more specific and requires that written notice be given 30 days in advance. However, since involuntary terminations are a relatively infrequent occurrence, we consider the financial impact on dialysis facilities to be negligible.

We estimate that 569 facilities will need 1 hour at $15 an hour on an annual basis to provide the required disclosure for a total annual cost of $8,535 ($569 \times 1 \times 15$). This is based on the assumption that the disclosure will be standardized and will not be required by the majority of facilities.

4. Quality Assessment and Performance Improvement

Existing regulations are not comparable to the proposed rule's requirement that the facility develop, implement, maintain, and evaluate a data-driven QAPI program. However, quality improvement efforts are considered part of the professional staff's job and the renal community has developed considerable consensus in recent years in regard to clinical performance data. The top 5 dialysis chains, representing two-thirds of all dialysis facilities are already collecting and reporting standardized data on 14 data elements, some of which are reported to the USRDS.

This proposed rule simply requires the facilities to use this data internally, in a formal QAPI program that each facility has the flexibility to develop to suit its own purposes. The two-thirds of dialysis facilities in the top five chains are already complying with this requirement and many others also consider use of this data as part of their standard practice. We estimate that the QAPI requirements would impose a burden on no more than 10 percent of the dialysis facilities (that is, 473 facilities).

Assuming that a facility were initiating a QAPI program only as a result of this proposed rule, this may entail a 1-hour meeting of 4 staff persons quarterly, with each staff person having an additional hour of work each month beyond the meeting (that is, 16 staff hours of meeting time + 48 staff hours beyond meetings = 64 hours annually). Assuming that the average staff cost is $25, the total additional cost to the facility would be $1,600 annually. The total cost for 473 facilities would be $756,800.

5. Medical Records

In the proposed rule, essential requirements in regard to retention, preservation, and transfer of medical records would be retained. However, the existing regulations are highly prescriptive in not only requiring the designation of a medical records supervisor, but in detailing that person's duties, specifying categories of information to be included in the medical record, requiring written policies and procedures to protect medical records information, and even addressing spatial issues in regard to the maintenance and processing of medical records. The proposed rule would delete many of these requirements, giving the facility flexibility in deciding how the medical records are to be maintained and what is to be in them, as long as they facilitate positive patient outcomes. This reduces burden on the dialysis facilities. We estimate that this will save the typical facility about 40 hours of a medical records professional's time, at $15 per hour, that is, $600 annually for an overall savings of $2,841,000.

6. Governance

The existing regulations specify the minimum requirements for CEO education and experience, whereas the proposed rule would delete these requirements.

However, the proposed rule would add new requirements, for a training program for water treatment system technicians and a written training program for dialysis patient care technicians, in regard to the operation of kidney dialysis equipment and machines and the provision of patient care. This training program would be developed or adopted by the facility and must be approved by the medical director and the governing body of the facility. The water system training program may be written, audiovisual, or computer based. Since the major dialysis chains all have training programs for their dialysis patient care technicians and water treatment technicians, and the majority of dialysis facilities are affiliated with these chains, a large portion of facilities already meet this requirement. In addition, at least 11 States already have some form of credentialing (training; competency exam; certification) requirements for dialysis patient care technicians, so dialysis facilities in these States, if they are unaffiliated with a major chain, may simply declare that meeting the State credentialing requirement is equivalent to completion of their training program. Even facilities that are not affiliated with a major dialysis chain and are in a State where there are no credentialing requirements for dialysis technicians, are not likely to be burdened with the requirement to develop a dialysis training program, since they can request medical director and governing body approval to use a packaged curriculum that includes a water treatment system module, which has been developed by organizations in the renal field and is available to any dialysis facility without cost.

7. Clinical Performance Measures

The proposed rule would add a requirement that all dialysis facilities electronically collect and report ESRD CPM Project data on all patients. The data include several measures of dialysis adequacy, vascular access, anemia management and nutrition.

Any potential burden added by this requirement is mitigated by the following:

- More than half the dialysis facilities already collect data on at least 14 clinical performance measures, including measures that evaluate adequacy of dialysis treatment, anemia, nutritional level, vascular access, bone disease, and hypertension. Many units affiliated with the major dialysis chains have integrated their electronic data systems for quality management with their data systems for patient management, to minimize the data reporting burden. These facilities understand that it is important to collect and to use the data to allow an accurate comparison of the facility's performance relative to that of its peers, since these comparisons can serve to identify significant opportunities for improvement.
- CPM data is already reported to CMS on a voluntary basis for a 5 percent national sample of patients, so many facilities are already familiar with the data reporting and collection process.
- The CPM data set will become a part of the Consolidated Renal Operations in a Web-enabled Network (CROWN) data system, and CMS will supply VISION software free to dialysis facilities to permit them to enter CPM data electronically directly into the system. VISION is available for general use and is currently being used by 138 independent dialysis facilities. Any dialysis facility that chooses to voluntarily participate in the CPM Project will be allowed to do so before the publication of a final rule. This could substantially reduce the number of facilities that need to be brought on line before the effective date of the final rule.
- Training for purposes of implementing the CPM requirement will be provided by CMS and its ESRD Networks without cost to the dialysis industry, and some of the training will be done using an Internet Web tool.

However, we do estimate that there will be some additional costs involved in: (1) Travel costs to training sites for some dialysis facility or chain representatives; (2) computer hardware and Internet Service Provider (ISP) connections for some facilities; and (3) collecting and transmitting data on the residual patients who are not served by the major dialysis chains and who are not part of the 5 percent sample of patients in the current CPM project. The detail in these estimates is as follows:

- Estimated costs for travel to training sites will be approximately $200 for each facility/chain representative and we estimate that 2,000 persons will be sent for training, most representing chains of dialysis facilities. The total cost of travel to training would, then, be $400,000, and this would be only for the initial year of implementation;
- Very few dialysis facilities would have to purchase computer hardware to implement this requirement, possibly no more than 142 (3 percent of total facilities). We estimate the cost of this purchase to be $1,000. Thus, the total cost for purchasing hardware would be $142,000, and this would be only in the initial year of implementation. We estimate ISP costs to be $150 annually ($150 × 142 facilities = $21,300);
- The estimated 5 percent annual growth rate in the ESRD population would mean that in 2005 there will be approximately 337,839 ESRD beneficiaries. We believe that the larger chains are already collecting CPM data on approximately 65 percent of these patients. Since the CPM project requires submission of this data on a 5 percent sample, we assume that the burden is only in regard to 95 percent of the remaining 35 percent of patients. Thus, we estimate that additional CPM data collection and reporting will be required for 112,331 patients annually (337,839 × .35 × .95). Based on current CPM project norms, we assume: One-half hour to abstract the data from the medical record by staff who are typically paid $25 per hour, for a cost of $1,404,142 (112,331 × .5 × $25) annually; and key-entry at the rate of 12 patients per hour by staff who are typically paid $12 per hour, for a cost of $112,331 annually.

Thus, in the first year of implementation, the total financial impact on the dialysis facilities of implementing the CPM requirement is estimated to be $2,079,774; thereafter, the cost would be approximately $1,537,774 ($1,404,142 + $112,331 + $21,300) annually for collecting and

transmitting the data and paying the ISP.

COST ESTIMATE FOR THE COLLECTION OF CPM DATA

$400,000	for travel to training (first year).
$142,000	for computer hardware (first year).
$1,537,474	for abstracting & key-entry of CPM data and ISP annually.
$2,079,774	Total

The following chart provides an overall estimate of the impact of the proposed rule:

OVERALL IMPACT OF THE PROPOSED RULE ON THE ECONOMY

4,735 facilities disaster planning burden @ $200	=	−$947,000
1,136 facilities (24%) LSC upgrades @ $1,960	=	+2,226,560
3,835 facilities (81%) purchasing AEDs @ $3,000	=	+7,670,700
4,735 facilities (patient rights distribution) @ $30	=	−142,050
473 facilities (QAPI) @ $1,600	=	+756,800
4,735 facilities (medical records burden) @ $600	=	−2,841,000
569 facilities (30-day discharge notice) @ $15	=	+8,535
CPM reporting requirement (detailed above)	=	2,079,774
Total impact on the economy	=	+8,812,319

C. Anticipated Effects of the Revised ESRD Conditions on Suppliers of ESRD Services

The Medicare conditions for coverage for ESRD facilities have not been revised in their entirety since their original publication in 1976. The revisions in this proposed rule reflect, for the most part, advances in dialysis technology and standard care practices. Transplant centers will not be affected because they are not included in this rule. One of the major purposes of this revision is to be responsive to regulatory reform initiatives, eliminating unnecessary procedural requirements and focusing on better patient outcomes of care.

D. Alternatives Considered

1. Maintenance of Existing Regulations

One alternative would be to keep the existing regulations. However, the current regulations inhibit our ability to ensure better outcomes of patient care, collect electronic data for quality assurance and quality improvement, incorporate new CDC and AAMI guidelines and fire safety standards and reduce current facility burden by eliminating numerous process and procedural requirements.

2. Infection Control

One alternative was not proposing an exception to the CDC recommendation for monthly and semiannual screening for hepatitis C. We retained the exception because blanket screening for hepatitis C is not a Medicare-covered service.

Another alternative was to propose compliance with all of the CDC guidelines in the RR05 report rather than just the crucial ''Recommended Infection Control Practices for Hemodialysis Units At a Glance'' (At a Glance) requirements. However, although we encourage compliance with the entire report, we decided against proposing compliance with the entire report. Our rationale was compliance with guidelines in the entire report would reduce flexibility and add unnecessary burden for dialysis facilities since some of the guidelines exceed the scope of these health and safety requirements.

A third alternative was to propose compliance with AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities. The AIA guidelines provide instructions regarding dialysis unit design as it relates to infection control. While some states have adopted specific AIA guidelines as minimal standards, we believe it would be too burdensome on dialysis facilities to propose to incorporate AIA guidelines as federal requirements.

3. Water Quality

One alternative was to propose to continue to require compliance with portions of the current AAMI guidelines,—ANSI/AAMI RD5: 1992 Appendix B5. However, we decided to propose compliance with portions of the newer AAMI document—RD62: 2001 and additional requirements that are compatible with ANSI/AAMI RD52: 2004 because RD62 and RD52, are the state-of-the-art water quality guidelines. We have asked for comments on this proposal.

4. Reuse of Hemodialyzers and Bloodlines

One potential cost-saving alternative was to remove the proposal that dialyzers exposed to more than one germicide were acceptable for reuse. We decided against this proposal because exposure to different germicides may cause membrane leaks and we have no scientific evidence to support the safety of using dialyzers exposed to more than one germicide.

5. Physical Environment and Emergency Preparedness

One alternative was to remove the proposal that every dialysis facility have a defibrillator. We retained this proposal because a Seattle study (Becker, pp. 1509–1512) identified dialysis centers as having a relatively high incidence of cardiac arrests over a 7-year period. Also, automated external defibrillators are now required on airliners and in other public places because the technology is simple to use, staff can be trained on the use of such equipment, and the technology has been proven to save lives.

A second alternative was to propose a waiver or phase-in period for defibrillators in small rural satellite

dialysis facilities with very low utilization. We are considering this alternative and have requested public comments on the defibrillator proposal.

6. Patients' Rights

One alternative was to remove the proposal for advance directives. We retained this proposal because of the nature of ESRD and the aging dialysis population.

Another alternative considered was not proposing that dialysis facilities have an internal grievance procedure. We did not adopt this alternative because we believe an internal grievance process is essential to allow patients to express their concerns directly to the facility in which they receive dialysis.

7. Patient Assessment

One alternative was to include ''extremely frail patients'' in the proposal to reassess unstable patients monthly. This proposal was not adopted in order to ensure that dialysis facilities retain the flexibility to make clinical determinations on a case-by-case basis.

Another alternative was to remove the proposal for a 3-month timeframe to reassess new patients. We are aware that the dialysis industry has not reached consensus regarding the appropriate frequency for reassessments, and therefore, we have requested comments on the current proposal to reassess new patients 3 months after starting dialysis.

8. Patient Plan of Care

One alternative was to retain the existing requirement for an individualized care plan with a 6-month review and a long-term program with an annual review. We did not adopt this approach because it was less burdensome to propose a single individualized plan of care (without a long-term program) to be reviewed annually.

Another alternative was to propose to adopt specific evidence-based NKF–K/DOQI clinical practice guidelines as numerical minimum target values within the patient plan of care condition (that is, adequacy of dialysis and anemia management). This issue is discussed in detail in the preamble and we are requesting public comments on the issue.

9. Quality Assessment and Performance Improvement

One alternative was to propose a QAPI program without specific threshold criteria. We determined, based on the work of the NFK–K/DOQI committees (adequacy, nutrition, anemia, and vascular access), AAMI guidelines (reuse), and specific recommendations from the OIG (medical error identification and patient satisfaction) that there was sufficient basis to include 7 basic criteria. We have requested public comment on QAPI.

10. Special Purpose Renal Dialysis Facilities

One alternative was to remove this condition entirely based on historically low levels of participation. We determined that eliminating this condition would be detrimental to the small number of vacation camps that choose to participate and it would also inhibit access to care during natural disasters.

Another alternative was to retain the current 8-month certification period and the current certification requirements. We believe that the current certification requirements are onerous; we believe that this is demonstrated by the lack of participation in Medicare by vacation camps. We believe proposing to reduce the number of certification requirements addresses this issue. The existing 8-month certification period is also excessive (that is, vacation camps are typically not open for 8 months and natural emergencies are of shorter duration). The current proposal represents a significant reduction in administrative burden for special purpose units.

11. Personnel Qualifications

One alternative was to retain the existing requirement that at least a licensed practical nurse must be on the premises during dialysis. We decided to propose that a registered nurse be on the premises during dialysis to protect patient health and safety and because this did not represent an increase in burden for dialysis units.

Other options were to propose no Federal requirements for dialysis technicians, or, to propose minimal Federal requirements for dialysis technicians and include proposals for competency testing and certification. A detailed discussion of this issue is in section VI.A.5 of this preamble. We determined that minimal Federal requirements are needed at this time because dialysis technicians are the primary caregivers in most dialysis facilities. However, we did not propose competency testing or certification and have requested public comment.

12. Medical Director

One alternative was to propose to eliminate the medical director condition and propose that other health care professionals run dialysis facilities. However, a June 2000 OIG report strongly recommended that we strengthen the role of the facility's medical director. In response to that recommendation, we proposed to retain the condition with a clarification of the medical director's responsibilities to include overseeing both the QAPI program and all involuntary patient transfers or discharges. We do not believe that this approach would impose an additional cost burden on dialysis facilities. We have requested public comments on these proposals.

13. Governance

One alternative considered was to remove the proposal for a 30-day advanced notice before involuntary patient discharge or transfer and retain the existing requirement (*see* § 405.2138(b)(2)) for patients to be ''given advance notice to ensure orderly transfer or discharge.'' We did not adopt this alternative because: (1) A 30-day advance notice for discharge and transfer has been consistent with the existing requirements in NFs, SNFs, and hospital swing-beds for over 12 years; (2) the dialysis patient population is increasingly older and many are nursing home residents with co-morbid conditions; and (3) large dialysis chains have emerged that can offer more flexibility and options for a patient involuntarily discharged from a facility by providing numerous units nearby or within commuting distance of that patient's place of residence. We have added a proposal to waive the 30-day notice under unusual circumstances.

This proposed rule contains a requirement for every dialysis facility to report ESRD CPM Project data to CMS. One option considered was to propose that less than 100 percent of facilities be required to participate. However, section 4558(b) of Pub. L. 105–33 requires CMS to monitor the quality of care delivered to dialysis patients. To date, CMS has been collecting a 5 percent CPM patient sample on a voluntary basis. CPM electronic data collection has been pilot-tested and is expected to be ready for general use in 2005. A gradual voluntary phase-in will be undertaken for facilities that want to participate before full implementation. We believe that 100 percent CPM data collection is necessary to comply with the intent of the statute. The large chain dialysis facilities and many other dialysis facilities already collect this data for benchmarking and quality improvement purposes, and therefore, this will not create a significant new burden for the industry. However, small rural facilities may have a difficult time coming into compliance, and therefore,

we are considering a phase-in period for these facilities.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 494

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart U—Conditions for Coverage of End-Stage Renal Disease (ESRD) Services

1. The authority citation for part 405, subpart U continues to read as follows:

Authority: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b-8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

2. The title of the subpart is revised to read as follows:

Subpart U—Conditions for Coverage for Suppliers of Renal Transplantation Services and Requirements for ESRD Networks

§§ 405.2100, 405.2101, 405.2135 through 405.2164, and 405.2180 through 405.2184 [Removed and Reserved]

3. Sections 405.2100, 405.2101, 405.2135 through 405.2164, and 405.2180 through 405.2184 are removed and reserved.

4. Section 405.2102 is revised to read as follows:

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

ESRD Network organization. The administrative governing body to the network and liaison to the Federal government.

Histocompatibility testing. Laboratory test procedures which determine compatibility between an organ donor and a potential organ transplant recipient.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Organ procurement. The process of acquiring donor organs. (See definition of Organ procurement organization in § 486.302 of this chapter.)

Renal transplantation center. A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

Transplantation service. A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

Transplantation surgeon. A person who—

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 410.5 [Amended]

2. In § 410.5(a), the reference ''Part 405, subpart U'' is revised to read ''Part 494''.

§ 410.50 [Amended]

3. In § 410.50(b), the reference ''§ 405.2163(b)'' is revised to read ''§ 494.130''; and the reference ''subpart M of part 405'' is revised to read ''part 494''.

§ 410.52 [Amended]

4. Section 410.52 is amended as follows:

a. In paragraph (a)(4), the reference to ''§ 405.2163'' is revised to read ''§ 494.90(a)(3)''.

b. In paragraph (b), the parenthetical statement ''(Section 405.2137 of this chapter contains specific details.)'' is revised to read ''(Section 494.90 of this chapter contains details on patient plans of care.)''

§ 410.152 [Amended]

5. In § 410.152(e)(1), ''subpart U of part 405'' is revised to read ''part 494''.

§ 410.170 [Amended]

6. In § 410.170(c), the reference to ''§ 405.2137(b)(3)'' is revised to read ''§ 494.90''.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

2. In § 413.170, paragraph (a) is revised to read as follows:

§ 413.170 Scope.

This subpart implements sections 1881(b)(2) and (b)(7) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis furnished in or under the supervision of a dialysis facility under part 494 of this chapter (referred to as ''facility''). For purposes of this section and §§ 413.172 through 413.198, ''outpatient maintenance dialysis'' means outpatient dialysis provided by a dialysis facility, home dialysis or self-dialysis as defined in

§ 494.10 of this chapter and includes all items and services specified in §§ 410.50 and 410.52 of this chapter.

* * * * *

3. In § 413.172, paragraph (b) is revised to read as follows:

§ 4l3.172 Principles of prospective payment.

* * * * *

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered outpatient maintenance dialysis. Approved ESRD facility means—

(1) Any independent or hospital-based facility (as defined in accordance with § 413.174(b) and (c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

* * * * *

§ 413.198 [Amended]

4. In § 413.198(a), the phrase ''approved under subpart U of part 405,'' is revised to read ''under part 494''.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. Part 414 is amended as follows:

1a. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

§ 414.330 [Amended]

2. In § 414.330(a)(2)(iii)(B), the reference ''subpart U of part 405'' is revised to read ''part 494''; and in § 414.330(a)(2)(iii)(B)(l), the reference to ''subpart U'' is changed to read ''part 494''.

3. In § 414.330(a)(2)(iii)(B)(*1*) the references ''subpart U'' are revised to read ''part 494'.

4. In § 414.330(a)(2)(iii)(B)(*7*) the references ''subpart U'' are revised to read ''part 494'.

5. Section 414.330(a)(2)(iii)(C) is added to read as follows:

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) * * *

(iii) * * *

(C) Agrees to report to the ESRD facility providing support services, every 30 days, all data for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

1. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1895hh).

2. In § 488.60 paragraph (a) is revised to read as follows:

§ 488.60 Special procedures for approving end stage renal disease facilities.

(a) *Consideration for approval.* An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494 of this subchapter, must secure a determination by the Secretary. To secure a determination, the facility must submit the following documents and data for consideration by the Secretary:

(1) Certification by the State agency referred to in § 488.12 of this part.

(2) Data furnished by ESRD network organizations and recommendations of the Public Health Service concerning the facility's contribution to the ESRD services of the network.

(3) Data concerning the facility's compliance with professional norms and standards.

(4) Data pertaining to the facility's qualifications for approval or for any expansion of services.

* * * * *

3. A new subpart H, consisting of §§ 488.604, 488.606, 488.608, and 488.610, is added to read as follows:

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End Stage Renal Disease (ESRD) Facilities

Sec.

488.604 Termination of Medicare coverage.
488.606 Alternative sanctions.
488.608 Notice of alternative sanction and appeal rights: Termination of coverage.
488.610 Notice of appeal rights: Alternative sanctions.

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End Stage Renal Disease (ESRD) Facilities

§ 488.604 Termination of Medicare coverage.

(a) Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this subchapter will result in termination of Medicare coverage of the services furnished by the supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required at § 494.160 of this subchapter, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this subchapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

§ 488.606 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of alternative sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the

requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

§ 488.608 Notice of alternative sanction and appeal rights: Termination of coverage.

(a) *Notice of alternative sanction.* CMS gives the supplier and the general public notice of the alternative sanction and of the effective date of the sanction. The effective date of the alternative sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this subchapter.

§ 488.610 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply an alternative sanction specified in § 488.606(b), the following rules apply:

(a) CMS gives the facility notice of the proposed alternative sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the alternative sanction, a written notice that specifies the effective date and the reasons for the alternative sanction.

1. Part 494 is added to read as follows:

PART 494—CONDITIONS FOR COVERAGE FOR END STAGE RENAL DISEASE FACILITIES

Subpart A—General Provisions

Sec.

494.1 Basis and scope.
494.10 Definitions.
494.20 Condition: Compliance with Federal, State, and local laws and regulations.

Subpart B—Patient Safety

494.30 Condition: Infection control.
494.40 Condition: Water quality.
494.50 Condition: Reuse of hemodialyzers and bloodlines.
494.60 Condition: Physical environment.

Subpart C—Patient Care

494.70 Condition: Patient rights.
494.80 Condition: Patient assessment.
494.90 Condition: Patient plan of care.
494.100 Condition: Care at home.
494.110 Condition: Quality assessment and performance improvement.
494.120 Condition: Special purpose renal dialysis facilities.
494.130 Condition: Laboratory services.

Subpart D—Administration

494.140 Condition: Personnel qualifications.
494.150 Condition: Medical director.
494.160 Condition: Relationship with the ESRD network.
494.170 Condition: Medical records.
494.180 Condition: Governance.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 494.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following provisions:

(1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation.

(2) Section 1138(a)(1)(B) of the Act, which requires hospitals to be members and abide by the rules and requirements of the Organ Procurement and Transplantation Network.

(3) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution.

(4) Section 1861(s)(2)(F) of the Act, which describes ''medical and other health services'' covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies.

(5) Section 1862(a) of the Act, which specifies exclusions from coverage.

(6) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of recombinant epoetin alpha (EPO).

(7) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113), which requires Federal agencies to achieve greater reliance on voluntary standards and emphasize, where possible, the use of standards developed by private, consensus organizations.

(b) *Scope.* The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

§ 494.10 Definitions.

As used in this part—

Dialysis facility means an entity that provides (1) outpatient maintenance dialysis services; or (2) home dialysis training and support services; or (3) both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter), or a self-care dialysis unit that furnishes only self-dialysis services.

Discharge means the termination of patient care services by a dialysis facility.

Furnishes directly means the ESRD facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.

Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in § 494.100(a) of this part.

Interdisciplinary team means the group of persons, specified § 494.80 of this part, responsible for providing patient care to each dialysis patient.

Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.

Transfer means a temporary or permanent move of a patient from one dialysis facility to another that requires a transmission of the patient's medical record to the facility receiving the patient.

§ 494.20 Condition: Compliance with Federal, State, and local laws and regulations.

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure, staff licensure and other personnel staff qualifications, fire safety, equipment, building codes, drugs, medical device usage, and any other relevant health and safety requirements.

Subpart B—Patient Safety

§ 494.30 Condition: Infection control.

The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and

any adjacent hospital or other public areas.

(a) *Standard: Procedures for infection control.* The facility must demonstrate that it follows standard infection control precautions by implementing—

(1) The ''Recommended Infection Control Practices for Hemodialysis Units at a Glance,'' with the exception of screening for Hepatitis C, found in ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients' Morbidity and Mortality Weekly Report, volume 50 number RR05, April 27, 2001, pages 20 and 21, developed by the Centers for Disease Control and Prevention, which are incorporated by reference, to prevent and control cross-contamination and the spread of infectious agents. Incorporation by reference of the CDC ''Recommended Infection Control Practices for Hemodialysis Units at a Glance,'' was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1]

(2) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and

(3) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—

(i) Handling, storage, and disposal of potentially infectious waste; and

(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

(b) *Standard: Oversight.* The facility must—

(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; and

(2) Designate a registered nurse as the infection control or safety officer, responsible for—

(i) Maintaining current infection control information including the most current Centers for Disease Control and Prevention guidelines for the proper techniques in the use of vials and ampules containing medication;

(ii) Reporting infection control issues to the dialysis facility's chief executive officer or administrator (see § 494.180(a) of this part) and the quality improvement committee; and

(iii) Making recommendations regarding infection control training and improvements.

(c) *Standard: Monitoring.* The facility must—

(1) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; and

(2) Develop recommendations to minimize infection transmission and take actions to reduce future incidents.

(d) *Standard: Reporting.* The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

§ 494.40 Condition: Water quality.

The facility must be able to demonstrate the following:

(a) *Standard: Water purity.* Water used for dialysis meets the following water quality standards and equipment requirements of the Association for the Advancement of Medical Instrumentation (AAMI) published in ''Water Treatment Equipment for Hemodialysis Applications,'' ANSI/AAMI RD62: 2001, which are incorporated by reference. Incorporation by reference of the AAMI Water Treatment Equipment for Hemodialysis Applications, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[2]

(1) Incorporated water quality requirements are those listed in sections—

(i) 4.2.1 and 5.2.1, Water Bacteriology;

(ii) 4.2.2 and 5.2.2 Maximum Level of Chemical Contaminants; and

(iii) 4.3, Water Treatment Equipment requirements.

(2) The requirements for frequency of water purity testing to insure meeting the AAMI limits specified in paragraphs (a)(1)(i) and (ii) of this section are as follows:

(i) Bacteria and bacterial endotoxin levels of water/dialysate must be monitored—

(A) In established systems at least monthly;

(B) In newly-installed systems at least weekly until an established pattern of compliance can be demonstrated;

(C) In accordance with the requirements of AAMI published in ''Dialysate for Hemodialysis,'' ANSI/AAMI RD52:2004 section 7.2.1, which are incorporated by reference. Incorporation by reference of the AAMI Dialysate for Hemodialysis was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[3]

(ii) Chemical analysis of water purity must be done at least once a year and when—

(A) The system is installed;

(B) Membranes are replaced, if using a reverse osmosis system;

(C) Seasonal variations in source water suggest worsening water quality;

(D) Reverse osmosis rejection rates, which are monitored daily using continuous-reading monitors that measure product water conductivity, fall below 90 percent.

(b) *Standard: Reverse osmosis or deionization.* Each water treatment system must include reverse osmosis membranes or a deionization component with resistivity monitors.

(c) *Standard: Chlorine/chloramines.* The facility must ensure, on a daily basis, that the source water does not contain chlorine/chloramines or the facility must ensure that—

(1) The water treatment system includes a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank for chlorine/chloramine removal; and

(2) The water from the exit port of the first component or carbon tank which removes chlorine/chloramine is tested for chlorine/chloramine levels, at a minimum, before each patient shift or every 4 hours, whichever is shorter, during operation of the water treatment system.

(i) If the test results are greater than 0.50 mg/L for free chlorine or 0.10 mg/L for chloramines from the port of the initial component or carbon tank then the second component or carbon tank which removes chlorine/chloramine must be tested; and

(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (c)(2)(i) of this section the facility must—

(A) Immediately terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;

[1] This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD and at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202–741–6030, or got to *http://www.archives.gov./federal_register/code lowbar;of_federal_regulations/ibr_locations.html.*

[2] This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD and at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov./federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

[3] This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD and at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202–741–6030, or got to *http://www.archives.gov./federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(B) Immediately notify the medical director; and

(C) Take corrective action.

(d) *Standard: Corrective action plan.* Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.

(e) *Standard: Adverse events.* A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must —

(1) Obtain blood and dialysate cultures;

(2) Undertake evaluation of the water purification system; and

(3) Take corrective action.

(f) *Standard: Unused bicarbonate.* Once mixed, bicarbonate concentrate must be used within the timeframe specified by the manufacturer of the concentrate.

§ 494.50 Condition: Reuse of hemodialyzers and bloodlines.

The dialysis facility that reuses hemodialyzers or bloodlines must meet the requirements of this section. Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: General requirements for the reuse of hemodialyzers and bloodlines.* Certain hemodialyzers and bloodlines—

(1) May be reused for certain patients with the exception of Hepatitis B positive patients;

(2) Must be reused only for the same patient; and

(3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 501(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

(b) *Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines.* A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(1) Meet the requirements of AAMI published in ''Reuse of Hemodialyzers,'' third edition, ANSI/AAMI RD47:2002/A1:2003, which is incorporated by reference. Incorporation by reference of the ''Reuse of Hemodialyzers, third edition, RD47:2002/A1:2003'' was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[4]

(2) Reprocess hemodialyzers and bloodlines—(i) By following the manufacturer's recommendations; or

(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach, during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

(c) *Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.* In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:

(1) Monitor patient reactions during and following dialysis.

(2) When clinically indicated (for example, after adverse patient reactions), the facility must—

(i) Obtain blood and dialysate cultures; and

(ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.

(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

§ 494.60 Condition: Physical environment.

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

(a) *Standard: Building.* The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.

(b) *Standard: Equipment maintenance.* The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

(c) *Standard: Patient care environment.* (1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

(2) The dialysis facility must—

(i) Maintain a temperature within the facility that is comfortable for the majority of its patients; and

(ii) Make reasonable accommodations for the patients who are not comfortable at the temperature that is comfortable for the majority.

(d) *Standard: Emergency preparedness.* The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.

(1) *Emergency preparedness of staff.* The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:

(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of—

(A) What to do;

(B) Where to go;

(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility; and

(D) How to disconnect themselves from the dialysis machine if an emergency occurs.

(ii) Ensuring that, at a minimum, patient care staff maintain current CPR certification; and

(iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs;

(2) *Emergency preparedness patient training.* The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1)(i) of this section.

(3) *Emergency equipment and plans.* Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available. The facility must—

[4] This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD and at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202–741–6030, or got to: *http://www.archives.gov./federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(i) Have a plan to obtain emergency medical system assistance when needed; and

(ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary.

(e) *Standard: Fire safety.* (1) The dialysis facility must meet applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter).

(2) Chapter 5 of the 2000 edition of the Life Safety Code does not apply to a dialysis facility.

(3) If CMS finds that a State has a fire and safety code imposed by State law that adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.

(4) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

(i) The waiver would not adversely affect the health and safety of the dialysis facility's patients; and

(ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.

Subpart C—Patient Care

§ 494.70 Condition: Patients' rights.

The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.

(a) *Standard: Patients' rights.* The patient has the right to—

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;

(2) Receive all information in a way that he or she can understand;

(3) Privacy and confidentiality in all aspects of treatment;

(4) Privacy and confidentiality in personal medical records;

(5) Be informed about and participate, if desired, in all aspects of his or her care, including advance directives, and be informed of the right to refuse treatment and to refuse to participate in experimental research;

(6) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis;

(7) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

(8) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

(9) Be informed by a physician of his or her own medical status as documented in the patient's medical record unless the medical record contains a documented contraindication to do so;

(10) Be informed of services available in the facility and charges for services not covered under Medicare;

(11) Receive the necessary services outlined in the patient plan of care described in § 494.90 of this part;

(12) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;

(13) Be informed of the facility's internal grievance process;

(14) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;

(15) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and

(16) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

(b) *Standard: Right to be informed regarding the facility's discharge and transfer policies.* The patient has the right to—

(1) Be informed of the facility's policies for transfer, discharge, and discontinuation of services to patients; and

(2) Receive written notice 30 days in advance of the facility reducing or terminating ongoing care after following the procedure described in § 494.180(f) of this part. In the case of immediate threats to the health and safety of others, a shortened discharge procedure may be allowed.

(c) *Standard: Posting of rights.* The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network telephone complaint numbers, where it can be easily seen and read by patients.

§ 494.80 Condition: Patient assessment.

The facility's interdisciplinary team, consisting of, at a minimum, the patient (if the patient chooses) or the patient's designee, a registered nurse, a nephrologist or the physician treating the patient for ESRD, a social worker, and a dietitian, is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

(a) *Standard: Assessment criteria.* The patient's comprehensive assessment must include, but is not limited to, the following:

(1) Evaluation of current health status and medical condition, including co-morbid conditions.

(2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs.

(3) Laboratory profile and medication history.

(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoietin.

(5) Evaluation of factors associated with renal bone disease.

(6) Evaluation of nutritional status.

(7) Evaluation of psychosocial needs.

(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters).

(9) Evaluation of the patient's ability, interests, preferences, and goals, including level of participation in the dialysis care process; modality and setting, for example, home dialysis, including hemodialysis or peritoneal dialysis; and expectations for care outcomes.

(10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record.

(11) Evaluation of family and other support systems.

(12) Evaluation of current patient physical activity level.

(13) Evaluation of vocational and physical rehabilitation status and potential.

(b) *Standard: Frequency of assessment for new patients.*

(1) An initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment.

(2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90 of this part.

(c) *Standard: Assessment of treatment prescription.*

The adequacy of the patient's dialysis prescription, as described in § 494.90(a)(1) of this part, must be assessed on an ongoing basis as follows:

(1) *Hemodialysis patients.* At least monthly by calculating delivered Kt/V or an equivalent measure.

(2) *Peritoneal dialysis patients.* At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.

(d) *Standard: Patient reassessment.* In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted—

(1) At least annually for stable patients; and

(2) At least monthly for unstable patients including, but not limited to, patients with—

(i) Extended or frequent hospitalizations;

(ii) Marked deterioration in health status;

(iii) Significant change in psychosocial needs; or

(iv) Poor nutritional status, with unmanaged anemia and inadequate dialysis.

§ 494.90 Condition: Patient plan of care.

The interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based community-accepted standards.

(a) *Standard: Development of patient plan of care.* The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:

(1) *Dose of dialysis.* The interdisciplinary team must provide the necessary care and services to achieve and sustain the prescribed dose of dialysis.

(2) *Nutritional status.* The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective nutritional status. A patient's albumin level must be measured at least monthly.

(3) *Anemia.* The interdisciplinary team must provide the necessary care and services to achieve and sustain the expected hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. If a patient has hemoglobin less than 11 gm/dL or hematocrit of less than 33 percent, the dialysis facility must conduct an evaluation to determine whether the patient is an erythropoietin candidate. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoietin and store erythropoietin under refrigeration. The patient's response to erythropoietin, including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

(4) *Vascular access.* The interdisciplinary team must provide the necessary care and services to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions and other risk factors. The patient's vascular access must be monitored to prevent access failure, including monitoring of ateriovenous grafts and fistulae for stenosis.

(5) *Transplantation status.* When the patient is a transplantation referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the—

(i) Plan for transplantation, if the patient accepts to transplantation referral;

(ii) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or

(iii) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10) of this part.

(6) *Rehabilitation status.* The interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years).

(b) *Standard: Implementation of the patient plan of care.*

(1) The patient's plan of care—

(i) Must be completed by the interdisciplinary team;

(ii) Must be signed by the patient or the patient's designee.

(2) Implementation of the plan of care must begin within 10 calendar days after completion the patient assessment as specified in § 494.80 of this part.

(3) If the expected outcome is not achieved, the interdisciplinary team, must adjust the patient's plan of care to achieve the specified goals.

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician providing the ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically, while the hemodialysis patient is receiving in-facility dialysis.

(c) *Standard: Transplantation referral tracking.* The interdisciplinary team must track the results of each kidney transplant center referral and must monitor the status of any facility patients who are on the transplant wait list. The team must communicate with the transplant center regarding patient transplant status at least quarterly or more frequently if necessary.

(d) *Standard: Patient education and training.* The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation.

§ 494.100 Condition: Care at home.

A dialysis facility that is certified to provide services to home patients must ensure, through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients.

(a) *Standard: Training.* The interdisciplinary team must provide training to the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10 of this part) and when the home dialysis caregiver or home dialysis modality changes. The training—

(1) Must be provided by a dialysis facility that is approved to provide home dialysis services;

(2) For self-care, must be conducted by a registered nurse who meets the requirements of § 494.140(b)(2) of this part; and

(3) Must be conducted for each home patient and address the specific needs of the patient, in the following areas:

(i) The nature and management of ESRD;

(ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hematocrit level of at least 33 percent or a hemoglobin level of 11 gm/dL;

(iii) Implementation of a nutritional care plan;

(iv) How to achieve and maintain emotional and social well-being;

(v) How to detect, report, and manage potential dialysis complications;

(vi) Availability of support resources and how to access and use resources;

(vii) How to self-monitor health status and record and report health status information;

(viii) How to handle medical and non-medical emergencies;

(ix) Infection control precautions; and

(x) Proper waste storage and disposal procedures.

(b) *Standard: Home dialysis monitoring.* The dialysis facility must—

(1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and

(3) Maintain this information in the patient's medical record.

(c) *Standard: Support services.*

(1) A dialysis facility must furnish directly home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company, that include, but are not limited to, the following:

(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.

(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

(iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meet the measurable and expected outcomes as specified in § 494.90 of this part.

(iv) Patient consultation with members of the interdisciplinary team, as needed.

(v) Monitoring of the quality of water used by home hemodialysis patients in accordance with the requirements specified in § 494.40(a)(1)(i) and (ii) of this part and conducting an onsite evaluation of the water system. The dialysis facility must correct the water quality of the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—

(A) Analysis of the water quality indicates contamination; or

(B) The home hemodialysis patient demonstrates clinical symptoms associated with water contamination.

(vi) Purchasing, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

§ 494.110 Condition: Quality assessment and performance improvement.

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, interdisciplinary quality assessment and performance improvement program. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(2) The dialysis facility must measure, analyze and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:

(i) Adequacy of dialysis.

(ii) Nutritional status.

(iii) Anemia management.

(iv) Vascular access.

(v) Medical injuries and medical errors identification.

(vi) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

(vii) Patient satisfaction and grievances.

(b) *Standard: Monitoring performance improvement.* The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Each facility must participate in ESRD network activities and pursue network goals.

(c) *Standard: Prioritizing improvement activities.* The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

(a) *Standard: Approval period.* The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12-month period.

(b) *Standard: Service limitation.* Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

(c) *Standard: Scope of requirements.* (1) *Scope of requirements for a vacation camp.* A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage—

(i) Infection control at § 494.30 of this part;

(ii) Water quality at § 494.40 of this part (except as provided in paragraph (c)(1)(viii) of this section;

(iii) Reuse of hemodialyzers at § 494.50 of this part (if reuse is performed);

(iv) Patients' rights and posting of patients' rights) §§ 494.70(a) and (c) of this part;

(v) Laboratory services at § 494.130 of this part;

(vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and (d) of this part;

(vii) Medical records at § 494.170 of this part; and

(viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to § 494.100(c)(1)(v) (home monitoring of water quality) of this part, in place of § 494.40 (water quality) of this part.

(2) *Scope of requirements for an emergency circumstance facility.* A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must additionally comply with the following conditions:

(i) § 494.20 (compliance with Federal, State, and local laws and regulations).

(ii) § 494.60 (physical environment).

(iii) § 494.70(a) through (c) (patient rights).

(iv) § 494.140 (personnel qualifications).

(v) § 494.150 (medical director).

(vi) § 494.180 (governance).

(d) *Standard: Physician contact.* The facility must contact the patient's physician, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in § 494.90 of this part).

(e) *Standard: Documentation.* All patient care provided in the special purpose facility is documented and forwarded to the patient's dialysis facility within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide or make available laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility, must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

Subpart D—Administration

§ 494.140 Condition: Personnel qualifications.

The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

(a) *Standard: Medical director.* (l) The medical director must be a physician who has completed a board approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis.

(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(b) *Standard: Nursing services.* (1) *Nurse manager.* The facility must have a nurse manager responsible for nursing services in the facility who must—

(i) Be a full time employee of the facility;

(ii) Be a registered nurse who meets the practice requirements of the State in which he or she is employed; and

(iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

(2) *Self-care training nurse.* The nurse responsible for self-care training must—

(i) Be a registered nurse who meets the practice requirements of the State in which he or she is employed; and

(ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

(3) *Charge nurse.* The charge nurse responsible for each shift must—

(i) Be a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed; and

(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis.

(4) *Staff nurse.* Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.

(c) *Standard: Dietitian.* The facility must have a dietitian who must—

(1) Be a registered dietitian with the Commission on Dietetic Registration;

(2) Meet the practice requirements in the State in which he or she is employed; and

(3) Have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian.

(d) *Standard: Social worker.* The facility must have a social worker who—

(1) Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education; and

(2) Meets the practice requirements for social work practice in the State in which he or she is employed.

(e) *Standard: Patient care dialysis technicians.* Patient care dialysis technicians must—

(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and

(2) Have a high school diploma or equivalency;

(3) Have completed at least 3 months experience, following a training program that is approved by the medical director and governing body. This experience must be under the direct supervision of a registered nurse, and be focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills including patient sensitivity training and care of difficult patients.

(f) *Standard: Water treatment system technicians.* Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

§ 494.150 Condition: Responsibilities of the medical director.

The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) of this part to be responsible for the delivery of patient care and outcomes in the facility. Responsibilities include, but are not limited to, the following:

(a) Quality assessment and performance improvement program.

(b) Staff education, training, and performance.

(c) Policies and procedures. The medical director must—

(1) Participate in the development, periodic review and approval of a ''patient care policies and procedures manual'' for the facility; and

(2) Ensure that—

(i) All policies and procedures relative to patient care and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and

(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f) of this part.

§ 494.160 Condition: Relationship with the ESRD network.

The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work.

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

(a) *Standard: Protection of the patient's record.* The dialysis facility must—

(1) Safeguard patient records against loss, destruction, or unauthorized use.

(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:

(i) The transfer of the patient to another facility.

(ii) Certain exceptions provided for in the law.

(iii) Provisions allowed under third party payment contracts.

(iv) Approval by the patient.

(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.

(3) Obtain written authorization from the patient or legal representative before releasing information that is not authorized by law.

(b) *Standard: Completion of patient records and centralization of clinical information.*

(1) Current medical records and those of discharged patients must be completed promptly.

(2) All clinical information pertaining to a patient must be centralized in the patient's record. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.

(3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

(c) *Standard: Record retention and preservation.* Patient records must be retained for a period of time not less than that required by State law or, in the absence of State law—

(1) *Adults.* 5 years from the date of the patient's discharge, transfer or death; or

(2) *Minors.* 3 years or until the patient reaches legal age under State law, whichever is longer, from the date of the patient's discharge, transfer or death.

(d) *Standard: Transfer of patient record information.* When a dialysis patient is transferred, the dialysis facility releasing the patient must send the patient's medical record and other information necessary in the patient's care or treatment to the receiving facility within 1 working day of the transfer.

§ 494.180 Condition: Governance.

The ESRD facility is under the control of an identifiable governing body, or designated person(s), with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the ESRD Network.

(a) *Standard: Designating a chief executive officer or administrator.* The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—

(1) Staff appointments;

(2) Fiscal operations;

(3) The relationship with the ESRD networks; and

(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program described in § 494.110 of this part.

(b) *Standard: Adequate number of qualified and trained staff.* The governing body or designated person responsible must ensure that—

(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients;

(2) A registered nurse is present in the facility at all times that patients are being treated;

(3) All employees have appropriate orientation to the facility and their work responsibilities upon employment;

(4) All employees have an opportunity for continuing education and related development activities; and

(5) There is an approved written training program specific to dialysis technicians that includes—

(i) Principles of dialysis;

(ii) Care of patients with kidney failure, including interpersonal skills;

(iii) Dialysis procedures and documentation, including the initiation, monitoring, and termination of dialysis;

(iv) Possible complications of dialysis;

(v) Water treatment;

(vi) Infection control; and

(vii) Safety; and

(viii) Dialyzer reprocessing, if applicable.

(6) When State requirements meet or exceed § 494.180(b)(5) the State requirements must be met.

(c) *Standard: Medical staff appointments.* The governing body—

(1) Is responsible for all medical staff appointments and credentialing, including attending physicians, physician assistants, and nurse practitioners; and

(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in § 494.110 of this part.

(d) *Standard: Furnishing services.* The governing body is responsible for ensuring that the dialysis facility furnishes directly (see § 494.10 of this part) services on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under § 494.100 of this part).

(e) *Standard: Internal grievance process.* The facility's internal grievance process must be implemented so that the patient may file a grievance with the facility without reprisal or denial of services. The grievance process must include—

(1) A clearly explained procedure for the submission of grievances;

(2) Timeframes for reviewing the grievance;

(3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.

(f) *Standard: Discharge and transfer policies and procedures.* The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless—

(1) The patient or payer no longer reimburses the facility for the ordered services;

(2) The facility ceases to operate;

(3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or

(4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team—

(i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s) and enters this documentation into the patient's medical record;

(ii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;

(iii) Attempts to place the patient in another facility and documents that effort; and

(iv) Notifies the State survey agency and the ESRD Network that services the area (where the facility is located) of the involuntary transfer or discharge.

(g) *Standard: Emergency coverage.* (1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.

(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must—

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

(h) *Standard: Furnishing data and information for ESRD program administration.* The dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

(2) Be submitted electronically in the format specified by the Secretary;

(3) Include, but not be limited to—

(i) Cost reports;

(ii) ESRD administrative forms;

(iii) Patient survival information; and

(iv) Existing ESRD clinical performance measures and any future clinical performance standards developed in accordance with the National Technology Transfer and Advancement Act process adopted by the Secretary.

(i) *Standard: Disclosure of ownership.* In accordance with §§ 420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Approved: July 19, 2004.

Tommy G. Thompson,

Secretary.

Note: This document was received at the Office of the Federal Register on January 25, 2005.

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Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 423

Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–0011–P]

RIN 0938–AN49

Medicare Program; E-Prescribing and the Prescription Drug Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This rule proposes to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). These proposed standards would be the foundation standards or the first set of final uniform standards for an electronic prescription drug program under the MMA, and represent the first step in our incremental approach to adopting final uniform standards that are consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 5, 2005.

ADDRESSES: In commenting, please refer to file code CMS–0011–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0011–P, PO Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (800) 743–3951 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the close of the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Gladys Wheeler, (410) 786–0273.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS–0011–P] and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please call (800) 743–3951.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders also can be placed by calling the order desk at (202) 512–1800 (or toll-free at (888) 293–6498) or by sending a fax to (202) 512–2250. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

A. Statutory Basis

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended Title XVIII of the Social Security Act (the Act) to establish the Voluntary Prescription Drug Benefit Program. Included in the provisions at section 1860D–4(e) of the Act is the requirement that prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically comply with final uniform standards adopted by the Secretary under an electronic prescription drug program.

On January 28, 2005, we published the Medicare Prescription Drug Benefit final rule that establishes the Prescription Drug Benefit Program and cost control and quality improvement requirements for prescription drug benefit plans. One of the provisions in that final rule requires Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) Organizations offering Medicare Advantage-Prescription Drug (MA–PD) plans, and other Part D sponsors to support and comply with electronic prescribing standards once

final standards are in effect, including any standards that are in effect before the drug benefit begins in 2006.

Although there is no requirement that providers write prescriptions electronically, in the Medicare Prescription Drug Benefit final rule, we stated that Part D sponsors that participate in the Part D program are required to support and comply with electronic prescribing. Providers that prescribe or dispense Part D drugs would be required to comply with the final standards only when prescription information or certain other related information is electronically transmitted once the final standards for those transactions are effective, which we anticipate will be in 2006, for this first set of final standards.

Section 1860D–4(e) of the Act specifies that initial standards, which are to be used in a pilot project that is to be conducted in calendar year 2006, must be adopted not later than September 1, 2005. This section of the Act also provides, however, that pilot testing is not required for those standards for which the Secretary, after consultation with affected standard setting organizations and industry users, determines there is ''adequate industry experience.'' Subsequent to the pilot project, the Secretary must promulgate final uniform standards not later than April 1, 2008. Those final uniform standards must become effective not later than 1 year after the date of promulgation of those final uniform standards. In addition, the Secretary is required to provide a report to the Congress by April 1, 2007 on his evaluation of the pilot project.

In the context of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions and code sets (TCS) requirements, a covered entity that conducts a covered transaction using electronic media must comply with the applicable transaction standard. Electronic media is defined under HIPAA to include both electronic storage media and transmission media, including the ''internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media.'' (45 CFR 160.103). However, given the development of new technologies, we invite public comment on applying this definition to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e-prescribing standards.

Section 1860D–4(e)(1) of the Act states that the final e-prescribing standards will govern ''prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically. * * *'' We believe the best reading of this language, as well of the intent of the Congress, is that the e-prescribing standards apply only to information regarding Part D eligible individuals enrolled in Part D plans—that is, enrollees of prescription drug plans (PDPs) (including employer-sponsored PDPs); fallback PDPs; Medicare Advantage Prescription Drug plans (MA-PD plans); and private fee for service plans, Medicare cost reimbursement plans, or PACE programs receiving Part D reimbursement. We believe this interpretation realizes the intent of the Congress, which in the Conference Report for the MMA, stated that e-prescribing standards are standards that apply to information, transmitted ''under an electronic prescription drug program conducted by a PDP or MA plan.'' (H.R. Conf. Rep. 108–391, 108th Cong., 1st Sess. at 455 (2003)) This statement contemplates that the e-prescribing standards would apply solely to information regarding Part D enrolled individuals, not simply to information regarding Part D eligible individuals who are not enrolled in a Part D plan. We have attempted to clarify the scope of these standards in the proposed definition of ''electronic prescription drug program'' in proposed § 423.159, and the ''General Rules'' in proposed § 423.160.

The requirements of the statute are as follows:

''(2) Program Requirements.—Consistent with uniform standards established under paragraph (3)—

''(A) Provision of Information to Prescribing Health Care Professional and Dispensing Pharmacies and Pharmacists.—An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered Part D drug:

''(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

''(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

''(B) Application to Medical History Information.—Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

''(C) Limitations.—Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(D) Timing.—To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

Section 1860D–4(e)(4)(B) of the Act also requires the National Committee on Vital and Health Statistics (NCVHS) to develop recommendations for standards, in consultation with specific groups of organizations and entities. Section 1860D–4(e)(4)(A) of the Act requires the Secretary to take these recommendations into consideration when developing, adopting, recognizing, or modifying initial uniform standards according to the schedule set forth above. The NCVHS process for developing and providing recommendations to the Secretary is detailed below at section B of this proposed rule.

In order to provide for efficient implementation of the requirements, section 1860D–4(e)(4)(C) of the Act requires the Secretary to conduct a pilot project to test initial standards developed under section 1860D–4(e)(4)(A) of the Act, prior to issuing the final standards that are promulgated in accordance with section 1860D–4(e)(4)(D) of the Act. Section 1860D–4(e)(4)(C)(ii) of the Act also permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. Under this exception, standards can be proposed and adopted through rulemaking as final standards without pilot testing, and would then become final standards under MMA.

In the preamble of the Medicare Prescription Drug Benefit proposed rule, published in the **Federal Register** August 3, 2004 (69 FR 46632–46863),

we solicited comments to help us identify consensus on e-prescribing standards ahead of the statutory timeframe and to help us identify and evaluate whether there is adequate industry experience with those standards. Concurrently, the NCVHS held hearings with various groups of constituencies on e-prescribing standards while identifying and examining standards for possible adoption by the Secretary. We attended each of these hearings as an active participant.

Under the MMA, proposed standards can be adopted as final standards prior to the dates specified in the statute because section 1860D–4(e)(1) of the Act provides for adoption ''as of such date as the Secretary may specify.'' The statute, moreover, only requires pilot testing for initial standards for which adequate industry experience is lacking and calls for final standards ''no later than April 1, 2008.'' Some comments submitted in response to the Medicare Prescription Drug Benefit proposed rule supported an accelerated timetable based on adequate industry experience with certain standards, while others advocated pilot testing of all standards because they felt adequate industry experience did not exist with any standard. We considered all public comments on this issue submitted in response to the Medicare Prescription Drug Benefit proposed rule, along with the NCVHS observations and associated recommended actions. Despite comments to the contrary, we believe that there is adequate industry experience for certain standards and have proposed those standards in this rule. The rationale for our preliminary conclusion that adequate industry experience exists is discussed later in this preamble. Finally, we believe that we have met the statutory requirement for industry consultation because we actively participated in the NCVHS process, and we requested and received industry comments on adequate industry experience with existing standards through the Medicare Prescription Drug Benefit proposed rule. We are also requesting comments in this proposed rule. The need for pilot testing of future standards will be determined when additional standards are recommended.

1. Initial Standards Versus Final Standards

It is important to emphasize that in section 1860D–4(e) of the Act there are distinct provisions for initial standards and final standards. Initial standards are standards for an electronic prescription drug program that the Secretary would adopt, develop, recognize, or modify before September 1, 2005, taking into consideration recommendations from the NCVHS. These standards will be subject to pilot testing that would occur during the 2006 calendar year. The results of the pilot project will be evaluated and, based upon those results, final standards would be published not later than April 1, 2008. In order to conduct the pilot project, the Secretary will enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals will electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with these standards. The Secretary will conduct an evaluation of the pilot project, and will submit a report to the Congress on the evaluation, not later than April 1, 2007.

Final standards are standards that would be adopted in regulations through the rulemaking process. Compliance with those final standards will be required when prescription information or certain other related information is electronically transmitted among Part D sponsors (as this term is defined in the Medicare Prescription Drug Benefit final rule) and prescribing health care professionals and dispensing pharmacies and pharmacists as specified at section 1860 D–4(e)(1) of the Act for covered Part D drugs prescribed for Part D enrolled individuals.

Final standards may be adopted by the Secretary as a result of the pilot project. However, if the Secretary, after consultation with affected standard setting organizations and industry users, determines that pilot testing is not required because there is adequate industry experience with the standards, those standards may be adopted as final without pilot testing.

We refer to the final standards proposed in this rule as foundation standards because they would be the first set of final standards adopted for an electronic prescription drug program. As mentioned above and discussed further below, we believe that adequate industry experience exists with respect to the standards proposed in this rule which allows us to propose and adopt these foundation standards as final standards without pilot testing.

2. State Preemption

Nearly every State allows for the electronic transmission of prescriptions. In recent years, many States have more actively legislated in this area. The scope and substance of this State activity, however, varies widely among the States.[1] The MMA addresses preemption of State laws at section 1860D–4(e)(5) of the Act as follows:

> (5) Relation to State Laws. The standards promulgated under this subsection shall supercede any State law or regulation that—
>
> (A) Is contrary to the standards or restricts the ability to carry out this part; and
>
> (B) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

We propose to interpret this section of the Act as preempting State law provisions that conflict with Federal electronic prescription program drug requirements that are adopted under Part D. We view it as mandating Federal preemption of State laws and regulations that are either contrary to the Federal standards, or that restrict the ability to carry out (that is, stand as an obstacle to) the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding covered Part D drugs for Part D enrolled individuals. Consequently, for a State law or regulation to be preempted under this express preemption provision, the State law or regulation would have to meet the requirements of both paragraphs (A) and (B). Furthermore, there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted. This interpretation closely reflects the language of the statute, and it is consistent with the presumption against Federal preemption of State law [2] and with the fundamental Federalism principles set forth in section 2 of Executive Order 13132. It is also consistent with the Department of Health and Human Service's (HHS) general position of deferring to State laws regulating the practice of pharmacy and the practice of medicine.

We understand that some industry representatives believe that the Congress intended this preemption provision to be much broader. For instance, some expressed the position that this statutory provision preempts all State laws that would in any way restrict the development of e-prescribing for all providers and payors. This position is based on the belief that the Congress

[1] Catizone, Carmen A. National Association of Boards of Pharmacy. Testimony before the NCVHS, July 29, 2004.

[2] *See Davies Warehouse Co.* v. *Bowles*, 321 U.S. 144, 153, 64 S.Ct. 474, 88 L.Ed. 635 (1944), *Pharmaceutical Research and Manufacturers of America* v. *Walsh*, 538 U.S. 644, 661, 123 S.Ct. 1855, 1867, 155 L.Ed.2d 889 (2003).

intended to preempt the field of e-prescribing through this provision in the MMA. It would require an interpretation that the word ''and'' between paragraphs (A) and (B) is disjunctive, that is, that ''and'' means ''or'' in this context. Under this interpretation, the operative language would be ''restricts the ability to carry out this part'' in paragraph (A), which arguably would enable the standards and requirements adopted for the Federal electronic prescription drug program to preempt all State laws and regulations that restrict the Secretary's ability to carry out the goals of an electronic prescription drug program, even if they are not related to covered Part D drugs, or Part D covered individuals. They contend that some States have existing statutory or regulatory barriers that could impede the success of e-prescribing; for example, laws and regulations that were drafted with only paper prescriptions in mind, which may not be well-suited to e-prescribing applications.

This interpretation, however, does not appear to comport with the use of the word ''contrary'' in the statutory language which generally establishes ''conflict preemption.'' This interpretation would seem to render paragraph (B) virtually meaningless and serve to establish ''field preemption.''

We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.

3. Anti-kickback Statute Safe Harbor and Stark Exception

Section 1860D–4(e)(6) of the Act requires the Secretary to promulgate regulations that provide for a ''safe harbor'' under the anti-kickback statute (section 1128B(b) of the Act) and an ''exception'' under the physician self-referral statute (section 1877 of the Act) for certain nonmonetary remuneration related to e-prescribing information technology items and services. The statute states that—

> The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128(b) [of the Social Security Act] and an exception to the prohibition under sub-section (a)(1) of section 1877 [of the Social Security Act] with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—
>
> (A) In the case of a hospital, by the hospital to members of its medical staff;
>
> (B) In the case of a group practice (as defined in section 1877(h)(4), by the practice to prescribing health care professionals who are members of such practice; and
>
> (C) In the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals.

We will propose the new Stark exception for electronic prescribing in a separate rulemaking to be published in the near future. The new safe harbor under the anti-kickback statute will be proposed by the Office of the Inspector General. In the meantime, where relevant, arrangements involving nonmonetary remuneration related to electronic prescription hardware, software, information technology and training must comply with an existing Stark exception (such as the exception for non-monetary compensation, 42 CFR 411.357(k), or the new community-wide health information technology exception, 42 CFR 411.357(u)) and must not violate the anti-kickback statute. They must also comply with similar state laws.

B. The NCVHS Process

Section 1860D–4(e)(4)(A) of the Act requires the Secretary to develop, adopt, recognize or modify initial uniform standards relating to the requirements for an electronic prescription drug program, not later than September 1, 2005, taking into consideration the recommendations from the NCVHS (as established under section 306(k) of the Public Health Service Act (43 U.S.C. 242k (k)) under subparagraph (B)). In particular, the role of the NCVHS in recommending uniform standards relating to the requirements for an electronic prescription drug program is outlined in section 1860D–4(e)(4)(B)(i) through (x) of the Act. It requires that in developing the recommendations, the NCVHS consult with the following:

- Standard setting organizations (as defined in section 1171(8) of the Act).
- Practicing physicians.
- Hospitals.
- Pharmacies.
- Practicing Pharmacists.
- Pharmacy Benefit Managers.
- State Boards of Pharmacy.
- State Boards of Medicine.
- Experts on e-prescribing.
- Other appropriate Federal agencies.

In response to the requirements of the Act for electronic prescription drug program standards, the NCVHS increased its number of meetings and held public hearings at which representatives of physicians, pharmacists, and experts on e-prescribing, among others, testified. The NCVHS also consulted with standard-setting organizations and accelerated the process for developing recommendations for the Secretary well in advance of the statutory requirement. At the July 21, 2004 Health Information Technology Summit, we announced our intent to accelerate the implementation of e-prescribing by proposing a first set of well-established standards for implementation by January 2006, when the Medicare Part D benefit begins.

To fulfill its responsibilities under the MMA's amendments to the Act, the NCVHS' Subcommittee on Standards and Security held public hearings on issues related to e-prescribing on March 30 and 31, 2004; May 25, 26, and 27, 2004; July 28–30, 2004; and August 17–19, 2004. These hearings included testimony from e-prescribing networks, providers, software vendors, and industry experts on patient safety, drug knowledge databases, and standards currently in use by the industry. Industry experts involved in e-prescribing studies and initiatives also presented information on the progress and findings of these studies. Following the hearings by the NCVHS Subcommittee on Standards and Security, the Subcommittee developed observations and associated recommended actions and presented them to the full NCVHS Committee for consideration. On September 2, 2004, the NCVHS sent a letter to the Secretary containing the observations and associated recommended actions for an electronic prescription drug program. The document included recommendations for the foundation standards that we are proposing and other long-term recommendations regarding pilot testing of other standards. For specific details, refer to the letter, available at *http://www.ncvhs.hhs.gov/040902lt2.htm*.

In order to develop and provide future recommendations to the Secretary, the NCVHS Subcommittee on Standards and Security plans to hold additional hearings on the state-of-the-art in e-prescribing, including testimony from a broad range of stakeholders. The NCVHS will be developing

recommendations for additional standards for consideration by the Secretary for testing and ultimate adoption through the rulemaking process. Readers interested in the NCVHS' hearing schedule, testimony presented at the hearings, and standards recommendations should consult the NCVHS Web site at *http://www.ncvhs.hhs.gov*.

C. Standards Design Criteria

Section 1860D–4(e)(3)(C) of the Act, specifies that the design criteria for electronic prescription drug program standards require that—

- The standards be designed so that, to the extent practicable, they do not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists;
- The standards be compatible with standards established under Part C of Title XI, standards established under section 1860D–4(b)(2)(B)(i) of the Act, and with general health information technology standards; and
- The standards be designed so that they permit the electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration (FDA) and the National Library of Medicine (NLM).

D. Current Prescribing Environment

According to 2002 data from the National Center for Health Statistics, Americans made more than 823 million visits to physicians' offices in 2000 and, according to the National Association of Chain Drug Stores (NACDS), four out of five patients leave a doctor visit with at least one prescription. More than 3 billion prescriptions are written in the United States (U.S.), and prescription medications are used by 65 per cent of the U.S. public in a given year, according to an Agency for Healthcare Research and Quality (AHRQ) 1999 report. Given this volume, even small improvements in quality that are attributable to e-prescribing may translate into significant cost benefits.

Today, physicians and other health care providers make their drug-prescribing decisions using whatever medical, medication, and eligibility information that is known or available to them. Then they give a handwritten prescription to the patient or fax it to the patient's pharmacy of choice. At the pharmacy, tasks are somewhat more automated. Through electronic claims, eligibility, and benefits submission, the dispensing pharmacist may learn about drug interactions, disease management concerns, the need for prior authorization, or lower cost alternatives. The pharmacist may then contact the prescriber by phone for approval of changes, refills, or renewals. This process can be very repetitive and time consuming for both the pharmacist's and the prescriber's office staff. According to some estimates, almost 30 percent of prescriptions require pharmacy call backs, resulting in 900 million prescription-related telephone calls that are placed annually.[3]

Many witnesses before the NCVHS have stated that the current prescribing process is prone to errors. Prescribers may not have access to the latest drug knowledge. They often do not have a completely accurate medication list or even medical history for their patient, and, as a result, may be unaware of potential drug-drug or drug-disease interactions or duplicate therapies. Pharmacists often have difficulty reading handwritten prescriptions and frequently have little or no information about the patient's condition for which the prescription is written. Contacting the prescriber by phone to clarify what is ordered and to make changes often results in delays for the patient and is time consuming for the prescriber and the pharmacist. There are disconnects between the prescriber and patient in the medication process, and little or no feedback is given to the prescriber on whether a prescription was filled or refilled. These disconnects can lead to preventable adverse drug events (ADEs) that are common and can be serious. According to the Center for Information Technology Leadership, more than 8.8 million ADEs occur each year in ambulatory care, of which over three million are preventable.[4] Medication errors account for one out of 131 ambulatory deaths.[5] In addition, the current system results in numerous and pervasive administrative and workflow inefficiencies, which affect costs and quality of care.

E. Current E-Prescribing Environment

E-prescribing is a complex process that usually involves a number of stakeholders, including prescribers, pharmacists and associated staff, vendors, hospitals and health systems, patients, health plans, and Pharmacy Benefit Managers (PBMs), among others. In a basic e-prescribing system, clinicians review, enter, manage, and sign prescriptions using a computerized system, instead of writing them on paper. The prescription is then electronically transmitted to a pharmacy. Currently, e-prescribing systems are available in a variety of graduated levels of technology with associated benefits for each level. The levels range in sophistication from a basic electronic drug information reference with dosing calculators and formulary information to medication ordering that is automatically linked to an electronic health record.

The value of e-prescribing in preventing medication errors is that each prescription can be electronically checked at the time of prescribing for dosage, interactions with other medications, and therapeutic duplication. E-prescribing could potentially improve quality, efficiency, and reduce costs by—

- Actively promoting appropriate drug usage, such as following a medication regimen for a specific condition;
- Providing information about formulary-based drug coverage, including formulary alternatives and co-pay information;
- Speeding up the process of renewing medications. An article reported that in a large primary care practice in Kokomo, Indiana, of 206 daily prescription-related calls, 97 calls were renewal requests;[6] and
- Providing instant connectivity between the health care provider, the pharmacy, health plans/PBMs, and other entities, improving the speed and accuracy of prescription dispensing, pharmacy callbacks, renewal requests, eligibility checks, and medication history.

The use of e-prescribing shows promise for improving Medicare operations by creating efficiencies in the administration of the Part D drug benefit, by decreasing costs in facilitating patient eligibility checks, promoting generic drug use, and creating timely interface with formularies. This also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.

According to industry surveys, usage rates for e-prescribing vary in number and in the level of sophistication of the electronic prescription system used. Somewhere between 5 percent and 18

[3] Hutchison, Kevin, SureScripts. Testimony before the NCVHS Subcommittee on Standards and Security, May 25, 2004.

[4] Center for Information Technology (CITL, a research organization chartered in 2002) *http://www.citl.org*, Wellesley, MA (781–416–9200) 2003 report: ''The Value of Computerized Order Entry in ambulatory Care.''

[5] Institute of Medicine, Committee on Quality in Healthcare in America. To Err is Human: Building a Safer Health System. Washington, DC, National Academy Press: 1999.

[6] Ennis K., Maus R. Kokomo Family Care: Automating the Clinical Practice. MGM Journal, 2001 (July/August): p. 8–11.

percent of physicians are estimated to be using e-prescribing of one sort or another, although usage is slowly increasing. Some of the barriers to increased usage of e-prescribing by physicians are the costs of buying and installing a system, the training involved, time and workflow impact, lack of reimbursement for costs and resources, and lack of knowledge about the benefits related to quality of care.

F. Evolution and Implementation of an Electronic Prescription Drug Program

In this regulation, we propose to adopt foundation standards (that is, standards that do not need to be pilot tested because adequate industry experience with those standards already exists). While the statute includes an exception to the pilot testing requirement for standards with adequate industry experience, it does not define the term. The concept was discussed throughout the NCVHS hearings, as industry participants debated whether specific standards should be recommended as foundation standards. We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions, and we solicit comments on these criteria:

- The standard is American National Standards Institute (ANSI) accredited. We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs.
- The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.
- The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected.

The Secretary has determined that pilot testing is not required for the standards proposed in this regulation because they meet the criteria for adequate industry experience. The need for pilot testing of future standards will be determined when additional standards are recommended.

Standards for e-prescribing must not only meet the specific requirements in section 1860D–4(e)(2) of the Act, but must also be compatible with standards adopted under Part C of Title XI (the Administrative Simplification provisions of HIPAA), and technology and general standards adopted under section 1860D–4(b)(2)(B)(i) of the Act. The standards should be vendor neutral and technology independent, and developed by Standards Development Organizations (SDOs) that are accredited by the ANSI.

The standards proposed in this regulation are important foundation standards, but do not represent the full set of standards that will be necessary to implement effectively an electronic prescription drug program. Further, at least one of the standards with which we are proposing to address basic e-prescribing functionality could be refined in the future ultimately to support more advanced functions. For example, the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard contains a segment that supports free text patient dosage instruction which could be enhanced to structure the patient instructions.

These proposed foundation standards are a first step toward a more complete set of standards required for an electronic prescription drug program under the MMA. Additional final standards will be identified, pilot tested, and proposed through separate processes in accordance with the time frames set forth in the statute and will build on these foundation standards.

In its September 2, 2004 letter to the Secretary, the NCVHS recommended that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future. We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.

G. Electronic Prescription Drug Program

Section 1860D–4(e)(2) of the Act specifies that an electronic prescription drug program for covered Part D drugs for Part D enrolled individuals shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the—

- Prescription;
- Information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization);
- Information on the drug being prescribed or dispensed and other drugs listed on the medication history;
- Information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments;
- Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed; and
- Information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

While it is important to note that, to the extent Part D sponsors, prescribers, and dispensers are covered entities under HIPAA, they must continue to abide by the applicable HIPAA standards, including those for privacy and security. All Part D Plans are covered entities under HIPAA, and we assume that many of the providers participating in Part D will likewise be covered entities. Providers are HIPAA covered entities if they engage in electronic transactions for which there are HIPAA standards. In general terms, under HIPAA, a covered entity is a health plan, a health care clearinghouse, and a health care provider who transmits any health information in electronic form in connection with a standard transaction. A standard transaction is defined as a transaction that complies with the applicable standards at § 162.1101 through § 162.1802. Two of the eight Administrative Simplification Standard Transactions conducted between providers and health plans at § 162.1101 through § 162.1802 (the NCPDP Telecommunication Standard for Health Care Claims, and the ASC X12N 270/271 Eligibility Inquiry and Response Standard for eligibility for a health plan queries), are proposed in this rule for e-prescribing foundation standards. The NCPDP Telecommunication Standard is proposed for eligibility inquiries and responses between pharmacies and health plans, and the ASC X12N 270/271 is proposed for eligibility inquiries between prescribers and health plans. Complete definitions for HIPAA covered entities and standard transactions are available at 45 CFR 160.103 and 45 CFR 162.103.

If a provider is not otherwise a covered entity under HIPAA, it would become a covered entity if it conducts an e-prescribing transaction that is also a HIPAA transaction, such as the 270/271 eligibility and response transactions. It should also be noted that disclosures of protected health information (PHI) in connection with an e-prescribing transaction that is not a HIPAA transaction would have to meet the minimum necessary requirements of the Privacy Rule if the entity is a covered entity. The Privacy Rule excludes from the minimum necessary requirements those disclosures that are required to comply with a HIPAA transaction standard. However, this exclusion would not apply to e-prescribing standards that are not also HIPAA standards, making compliance with minimum necessary a requirement, unless another exception applies.

The MMA requires the Secretary to develop, adopt, recognize or modify initial uniform standards related to the requirements of an electronic prescription drug program taking into consideration any recommendations from the NCVHS. The standards must be designated to enable transmission of basic prescription data to and from prescribers and dispensers, as well as the transmission of information about the patient's drug utilization history, possible drug interactions, the drug plan, and cost information. The design of the standards for an electronic prescription drug program must be consistent with the objectives of improving patient safety, quality of care, efficiencies and cost savings in the delivery of care, and meet the standards design criteria outlined in this section. The standards also must permit the use of appropriate messaging, according to section 1860D–4(e)(2)(d) of the Act, as it relates to the prescribing of drugs and permit patients to designate a dispensing pharmacy.

In its September 2, 2004 letter, the NCVHS provided its observations and associated recommended actions related to the standards needed for the interoperable electronic exchange of information for most of the categories of information enumerated in section 1860D–4(e)(2) of the Act. The key NCVHS recommendations concerning these functions and whether they are included in the NPRM are summarized in the table below:

Function	NCVHS Standards Recommendations—HHS Should:	Standard in NPRM
Provider and Dispenser Identifiers	Adopt NPI when it becomes available	No.
Prescription (Clinical drug)	Include in the 2006 pilot tests the RxNorm terminology in the NCPDP SCRIPT Standard.	No.
Drug order for new, renewals, cancellations, and change orders.	Recognize, as a foundation standard, the most current version of NCPDP SCRIPT for new prescriptions, prescription renewals, cancellations, and changes between prescribers and dispensers.	Yes.
Drug orders for fill status notification	Should include the fill status notification function of the NCPDP SCRIPT Standard in the 2006 pilot tests.	No.
Patient instructions (SIG)	Support NCPDP, HL7, and others (especially including the prescriber community) in addressing SIG (patient instruction) components in their standards.	No.
Medication history	Participate in and support rapid development of an NCPDP standard for a medication history message for communication from a payer/PBM to a prescriber.	Standard functionality identified.
Formulary and benefit coverage information.	Participate in and support the rapid development of an NCPDP standard for formulary and benefit information file transfer.	Standard functionality identified.
Eligibility inquiry and response	Recognize, as a foundation standard, the NCPDP Telecommunication Standard and the ASC X12N 270/271–Health Care Eligibility Benefit Inquiry and Response.	Yes.
Prior authorization	Support ASC X12N in their efforts to incorporate functionality for real-time prior authorization messages for drugs in the ASC X12N 278 Health Care Services Review.	No.
Drug-drug Interaction	No recommendations advanced. Subject to future NCVHS hearings.	No.
Medical History	No recommendations advanced. Subject to future NCVHS hearings.	No.
Exchange of medication history, and medical history for e-prescribing program.	No recommendations advanced. Subject to future NCVHS hearings.	No.
Electronic signature	No recommendations advanced. Subject to future NCVHS hearings.	No.

In section II of this proposed rule (Provisions of the Proposed Regulation), we describe the proposed requirements related to the use of the most current version of NCPDP SCRIPT for new prescriptions, prescription renewals, cancellations, changes between prescribers and dispensers, and ancillary messaging and administrative transactions, the NCPDP Telecommunication Standard, and the ASC X12N 270/271 transaction, for transmitting eligibility data between dispensers and Part D sponsors and between prescribers and Part D sponsors, respectively.

The NCVHS also observed that ''there are several areas in the foundation standards that do not support all the MMA requirements.'' As can be seen from the Table above, additional standards will be required to implement many of the functions of an electronic prescription drug program as envisioned by the MMA. Examples of some of the needed standards and associated issues are as follows:

• Provider and Dispenser Identifiers. The MMA does not expressly direct the Secretary to require the use of unique identifiers for prescribers and dispensers in e-prescribing transactions. However, the NCVHS found that it was important to address the issue of provider identifiers for various e-

prescribing standards it reviewed and, more generally, for an electronic prescription drug program. We agree. After assessing a number of candidate identifiers, the NCVHS further recommended the use of the National Provider Identifier (NPI) as the primary identifier for dispensers and prescribers, once it becomes available.

HHS is considering requiring the use of the NPI as the provider identifier for an electronic prescription program under Medicare Part D. We believe that it is necessary to have a unique identifier for these transactions. The NPI is the preferred option, because it is a standard that many entities will be required to use under HIPAA. If use of the NPI is required for e-prescribing transactions involving Medicare Part D drugs at the time the benefit is available in January 2006, prescribers, pharmacies, pharmacists, Part D sponsors and potentially other entities would be required to implement the NPI for e-prescribing transactions earlier than the current compliance date for the HIPAA covered transactions.

The NCVHS also urged HHS to accelerate the enumeration of all providers to support transition to the NPI for e-prescribing. We have been planning to enumerate HIPAA covered providers over the course of several years.

Accelerated NPI usage for e-prescribing, therefore, may not be possible, as HHS may not have the capacity to issue NPIs to all covered providers by January 1, 2006. Furthermore, there is a possibility that unforeseen system or budget concerns could delay provider enumeration, and, therefore, the date by which the NPI would be available for use in e-prescribing under Medicare Part D.

We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.

NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.

• Formulary and Medication History Standards. Adoption of standards for formulary representation and medication history would clearly enhance e-prescribing capabilities under Part D. Such standards would make it possible for the prescriber to obtain information on the patient's benefits, including the formulary status of drugs that the physician is considering prescribing, as well as information on medications the patient is already taking including those prescribed by other providers. Significant quality improvement and cost savings could result from the use of formulary and medication history standards.

The NCVHS noted that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer protocols established by RxHub, a national formulary and benefits information exchange. In response to industry testimony, RxHub communicated to the NCVHS its intent to submit its protocols to NCPDP to be considered for adoption as an ANSI-accredited standard. NCVHS considered ANSI accreditation to be a criterion in their recommendations process, and HHS proposes to adopt this as a criterion for determining adequate industry experience.

The NCVHS recommended that HHS actively participate in and support the rapid development of an NCPDP standard for formulary and medication history using the RxHub protocol as a basis, and indicated its belief that this appeared possible in time to adopt the standard as a foundation standard.

We propose to adopt, as foundation standards in the final rule, formulary representation and medication history standards, if certain characteristics are met and there is adequate industry experience with the standards. We would consider adopting an NCPDP standard for formulary and medication history that are based on the RxHub protocol.

We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:

• The standards are accredited by an ANSI-accredited standards development organization.

• The standards permit interface with multiple product, router, and point-of-care (POC) vendors.

• The standards provide a uniform means for—

+ Pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via POC systems; and

+ POC vendors to receive a range of formulary and benefit information through these services.

• The standards cover a range of formulary and benefit data, including information on the—

+ Formulary (for example, therapeutic classes and subclasses);

+ Formulary status (for example, drugs that the benefit plan considers to be ''on formulary'');

+ Preferred alternatives (including, but not limited to restrictions that may impact whether the plan will cover a drug being considered, such as quantity limits and need for prior authorization); and

+ Copayment (that is, not just the single copayment amount for the drug being considered, but the copayments for one drug option versus another).

We propose the following critical characteristics for medication history standards:

• The standards are accredited by an ANSI-accredited standards development organization.

• The standards permit interface with multiple product, router, and POC vendors.

• The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.

• The standards provide a uniform means for a Part D plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe, and may include the pharmacy that filled the prescription and the physician that wrote the prescription.

• Drug Information. Section 1860D–4(e)(2) of the Act specifies that an electronic prescription drug program

will include information on drug-drug interactions, warnings or cautions, and when indicated, dosage adjustments. Given that relevant e-prescribing standards must permit electronic exchange of drug labeling and drug listing information maintained by the FDA and the NLM, medication history standards should be compatible with those standards when they are adopted by the Secretary. While drug information standards will not be foundation standards, they will be supported in the future by the structured product label. While standards for providing this type of information on drugs have not yet been considered by the NCVHS and are not yet proposed, we anticipate proposing standards in the future through rulemaking because they are required by MMA and we believe that providing this information is essential to improving the safety and quality of medication management. We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.

• Medical History. Section 1860D–4(e)(2)(B) of the Act specifies that an electronic prescription drug program includes the electronic transmittal of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed. ''Medical history'' differs from ''medication history.'' ''Medication history'' refers to drugs that have been prescribed to the individual, while ''medical history'' relates more broadly to information about the patient's health care and health status (for example, allergies, laboratory test results, and chronic conditions).

The statute treats the electronic transmission of medical history differently from the electronic transmission of other information in an electronic prescription drug program. Section 1860D–4(e)(2)(B) of the Act specifies that the medical history provision is only effective ''on and after such date as the Secretary specifies and after the establishment of appropriate standards.'' We intend to propose standards for communicating medical history at a future date. The NCVHS has not yet provided recommendations on these standards. This proposed rule does not address data collection and storage in terms of research. We will consider any NCVHS recommendations in our design of the pilot project for 2006.

H. Summary of Status of Standards for an Electronic Prescription Drug Program

We recognize that the standards we are proposing do not provide all of the functions for which standards are required by section 1860D–4(e)(2) of the Act. At this time, we can only propose to adopt, as final standards, those standards with which there is adequate industry experience; otherwise, pilot testing is required by section 1860D–4(e)(4)(c) of the Act prior to the adoption of a standard as a final standard. We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:

• The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).

• The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).

• The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to as the NCPDP Telecommunication Standard).

We acknowledge that an e-prescribing program (including drug-to-drug interaction checking, dosage adjustments and information on the availability of lower cost therapeutic alternatives for which standards will be adopted in the future) is one part of a comprehensive Electronic Health Record (EHR) system with decision support functionality and must be interoperable with other functions of an EHR. The need for interoperability between these systems will become even more critical in the future when patient medical history standards are adopted. While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI-accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.

II. Provisions of the Proposed Regulation

[If you choose to comment on issues in this section, please include the caption ''PROVISIONS'' at the beginning of your comments.]

A. Proposed Change to Scope (Section 423.150)

Subpart D of part 423 implements provisions of several sections of the Act, including sections 1860D–4(c), 1860D–4(d), 1860D–4(e), 1860D–4(j), and 1860D–21(d)(3), as well as sections 102(b) and 109 of Title I of the MMA. Because section 1860D–4(e) of the Act pertains to standards for electronic prescription drug programs which require compliance by e-prescribing entities other than Part D plans, we propose to explicitly broaden the scope of subpart D. Therefore, we are proposing to modify the title of subpart D to read, ''Cost Control and Quality Improvement Requirements,'' and revise the description of the scope at § 423.150(c) to state expressly that this subpart sets forth requirements relating to electronic prescription drug programs

for prescribers, dispensers, and Part D sponsors.

B. Proposed Definitions

We propose to amend § 423.159 of the Medicare Prescription Drug Benefit final rule to add definitions pertinent to the e-prescribing process and to amend the title of the section to be consistent with the term ''Electronic Prescription Drug Program'' which we are proposing to define below. The proposed definitions are as follows:

- Dispenser means a person, or other legal entity, licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located, to provide drug products for human use on prescription in the course of professional practice.
- Electronic media shall have the same meaning as this term defined for purposes of HIPAA, in 45 CFR 160.103.
- E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.
- Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.
- Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.
- Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan.

C. Proposed Requirements for Part D Plans

The Medicare Prescription Drug Benefit final rule has specific language that requires Part D sponsors to support and comply with electronic prescription drug program standards relating to covered Part D drugs, for Part D enrolled individuals once final standards are effective. Effective January 1, 2006, Part D sponsors would be required to have an electronic prescription drug program and would be required to support electronic prescribing, once standards are in place.

Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy. The e-prescribing standards that these ''closed'' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards.

It is important to note that the NCVHS recommendation differs from the HIPAA transaction requirements. The preamble for the Transactions Rule (65 FR 50316–50317) discusses transmissions within a corporate entity requires covered entities to use the adopted transaction standards when conducting covered electronic transactions with other covered entities. The Transactions Rule also expressly states that if a covered entity conducts a covered transaction using electronic media within the same covered entity, it must conduct the transaction as a standard transaction (45 CFR 162.923). Consequently, whether the transaction is conducted within or outside the entity is immaterial with respect to whether compliance with the HIPAA transactions is required.

This issue is relevant to Medicare Part D in situations where an MA-PD plan, for example, is a staff-model HMO using an internal pharmacy. We solicit comment on whether Part D plans should be required to use the standards for e-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted e-prescribing standards.

D. Proposed Requirements for Prescribers and Dispensers

Part D sponsors would be required to comply with the applicable proposed standards in new § 423.160(b) when electronically transmitting prescriptions and prescription-related information. If prescribers and dispensers electronically transmit prescriptions and prescription-related information, they also would be required to comply with the applicable proposed standards in proposed § 423.160(b). These entities would be required to comply with the standards whether they transmit prescriptions or prescription-related information using electronic media, either directly or through an intermediary, through, for example, an e-prescribing network.

E. Proposed Standards

The Secretary has tentatively concluded that the proposed standards discussed below are not subject to pilot testing because adequate industry experience with these proposed standards already exists. Entities with electronic prescription drug programs would be required to comply with the proposed applicable standards no later than January 1, 2006.

1. Prescription

The NCPDP SCRIPT Standard contains a series of business processes, referred to as transactions, which are included in the NCPDP SCRIPT Standard. We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for the Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction—Filled; Prescription Fill Status Notification Transaction—Not Filled; and Prescription Fill Status Notification Transaction—Partial Fill). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.

We propose, in new § 423.160(b)(1), to adopt the following transactions of the NCPDP SCRIPT Standard, for communication of prescription information between prescribers and dispensers, as part of an electronic prescription drug program:

- New prescription transaction
- Prescription refill request and response transactions
- Prescription change request and response transactions
- Cancel prescription request and response transactions
- The following ancillary messaging and administrative transactions:
  + Get message transaction
  + Status response transaction
  + Error response transaction
  + Verification transaction
  + Password change transaction

We have determined that these transactions of the NCPDP SCRIPT

Standard meet our proposed criteria for adequate industry experience for the following reasons:

• First, the ANSI recognizes NCPDP as an accredited standards organization. The NCPDP SCRIPT Standard adheres to Electronic Data Interchange (EDI) for Administration Commerce and Transport (EDIFACT) and Accredited Standards Committee (ASC) standards.

NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization consisting of over 1,300 members representing virtually every sector of the pharmacy services industry. With over 25 years' experience in the pharmacy health care industry, NCPDP membership includes representatives from—

+ Chain and independent pharmacies;
+ Consulting companies and pharmacists;
+ Database management organizations;
+ Federal and State agencies;
+ Health insurers;
+ Health maintenance organizations;
+ Mail service pharmacy companies;
+ Pharmaceutical manufacturers;
+ Pharmaceutical services administration organizations;
+ Prescription service organizations;
+ Pharmacy benefit management companies;
+ Professional and trade associations;
+ Telecommunication and systems vendors;
+ Wholesale drug distributors; and
+ Other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

The NCPDP SCRIPT Standard is a voluntary consensus-based standard that was developed by NCPDP, and approved by full ballot voting in accordance with ANSI's procedures for due process, openness and consensus. More specifically, the NCPDP SCRIPT Standard transactions we propose for adoption have been used extensively for messaging between prescribers and retail pharmacies for new prescriptions, prescription refill requests, prescription fill status notifications, and cancellation notifications, as part of the Consolidated Health Informatics (CHI) Initiative. CHI is the health care component of President Bush's eGov Initiatives created under the President's Management Agenda.

• Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs. SureScripts, Inc. (SureScripts) selected the NCPDP SCRIPT Standard to serve as the foundation of their transaction engine software. SureScripts was founded by the National Community Pharmacists Association (NCPA) and the NACDS, which represent the interests of 55,000 chain and independent pharmacies. To date, SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 75 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with software companies who supply electronic health record and electronic prescribing applications to physician offices representing more than 50,000 current physician users.

• Third, the NCPDP SCRIPT Standard transactions we propose for adoption are recognized as the industry standard. Over 25 e-prescribing vendors (stand-alone and electronic health record integrated systems) which represent 80 percent of the Nation's covered lives are either using or actively programming to the NCPDP SCRIPT standard.

We do include, as part of the proposed foundation standards, the previously identified ancillary messaging and administrative transactions. These transactions are an integral part of the NCPDP SCRIPT Standard, providing the administrative functions to assure that prescription transactions are accurately exchanged. Industry experience with the adopted HIPAA transactions has shown the need for standard acknowledgement and error reports transactions. During the NVCHS hearings, the only transaction specifically mentioned as lacking industry experience was the Prescription Fill Status Notification Transaction and, thus, it has not been included in this proposed rule. Because these ancillary messaging and administrative transactions are an integral part of the NCPDP SCRIPT Standard, we believe that the industry has adequate experience with them, so as to be able to forego pilot testing. We solicit public comment on the adoption of the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as proposed foundation standards and whether there is adequate industry experience to forego pilot testing.

2. Eligibility

We are proposing, at new § 423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors.

The ASC X12N 270/271 transaction standards were adopted in August 2000 as the HIPAA standard for eligibility inquiry and response transactions between dentists, (medical) professionals, and institutions, on one hand, and health plans, or just between health plans.

We have determined that the ASC X12N 270/271 transaction standard meets the criteria for adequate industry experience for the following reasons:

• First, the ASC X12N 270/271 are ANSI-accredited standards.

• Second, the standards are adopted HIPAA standards. Use of the ASC X12N 270/271 transaction for conducting eligibility and response inquiries between providers and health plans and between two health plans has been required since October 16, 2003, at the latest. In May 1998, when adoption of this standard was proposed through notice and comment rulemaking, the majority of comments received expressed support for adopting this standard.

Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.

We are proposing to adopt, at proposed § 423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. We have determined that the NCPDP Telecommunication Standard meets our proposed criteria for adequate industry experience for the following reasons:

• First, these standards adhere to EDI for EDIFACT and ASC standards. As previously stated, NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization, with over 25 years experience in the pharmacy health care industry, and its membership consists of over 1,300 members representing virtually every sector of the pharmacy services industry. These standards are voluntary, consensus-based standards that were developed by NCPDP, and approved by full ballot voting in accordance with ANSI's procedures for due process, openness and consensus.

• Second, these standards are adopted HIPAA standards. In addition to being required standards for eligibility inquiries and responses between retail pharmacy dispensers and health plans, they are also required for submitting retail pharmacy drug claims.

According to the NACDS, over 4 billion claims were transmitted in 2003 using NCPDP standards. In May 1998, when adoption of these standards was proposed through notice and comment rulemaking, the majority of comments received expressed support for adoption.

• Third, these standards are recognized as industry standards and are used by 99 percent of the retail pharmacies and 95 percent of all pharmacies in conducting eligibility transactions.

If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the **Federal Register** of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.

When determining whether to waive notice and comment and whether to incorporate by reference multiple existing versions, we would consider the significance of any corrections or revisions to the standard as well as whether the newer version is ''backward compatible'' with the previously adopted version. In this context, we intend the term ''backward compatible'' to mean that the newer version would retain, at a minimum, the full functionality of the version previously adopted in regulation, and would permit the successful completion of the applicable e-prescribing transaction with entities that continue to use the previous version. We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR parts 160 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.

F. Compliance Date

The Secretary proposes January 1, 2006 as the compliance date for these proposed foundation standards. Beginning January 1, 2006, prescribers and dispensers that conduct e-prescribing transactions for which standards are adopted, Part D sponsors would be required to use the standards proposed in this rule for transactions involving prescription or prescription-related information regarding Part D enrolled individuals. Compliance is required whether the entity conducts e-prescribing transactions directly or through an intermediary. The Secretary determined that compliance with these foundation standards should be consistent with and coincide with compliance for the Medicare Prescription Drug Program. In January 2006 when entities begin participation in the Medicare Prescription Drug Program, these proposed standards will be available for them to use in their electronic prescription drug program transactions for Medicare Part D drugs for Part D enrolled individuals.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 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:

• Whether the information collection is necessary and useful to carry out the proper functions of the agency.

• The accuracy of the agency's estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

Section 423.160 Standards for an Electronic Prescribing Program

Discussion: The emerging and increasing use of health care EDI standards and transactions has raised the issue of the applicability of the PRA. It has been determined that a regulatory requirement mandating the use of a particular EDI standard constitutes an agency-sponsored third-party disclosure as defined under the PRA.

Therefore, as a third-party disclosure requirement subject to the PRA, Part D sponsors offering qualified prescription drug coverage must support and must comply with electronic prescription standards relating to covered Part D drugs, for Part D enrolled individuals as would be required under § 423.160.

However, the requirement that Part D sponsors support electronic prescription drug programs in accordance with standards set forth in this section, as established by the Secretary, does not require that prescriptions be written or transmitted electronically by prescribers or dispensers. After the promulgation of this first set of final standards, these entities will be required to comply with the adopted final standards only if they transmit prescription information electronically as discussed in section 1860D–4(e)(1) and (2) of the Act.

Testimony presented to the NCVHS indicated that most health plans/PBMs currently have e-prescribing capability either directly or by contracting with another entity. Therefore, we do not believe that conducting an electronic prescription drug program would be an additional burden for those plans.

Since these standards are already in use, we believe the requirement to adopt these standards constitutes a usual and customary business practice and the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to OMB for its review of these information collection requirements.

If you comment on any of 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 Issuances Group, Attn: John Burke, CMS–0011–P 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: Christopher Martin, CMS Desk Officer, CMS–0011–P, *Christopher_Martin@omb.eop.gov.* Fax (202) 395–6974.

IV. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption ''IMPACT ANALYSIS'' at the beginning of your comments.]

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in costs and benefits in any 1 year). Our estimate is that this rulemaking has ''economically significant'' benefits as measured by the $100 million standard, and is also, therefore, a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis.

Statistics from the Henry J. Kaiser Family Foundation indicate that more than 3.1 billion retail prescriptions were written in the United States in 2003, with the average cost for a prescription ranging from $45 to $67, totaling $154 billion. Individuals who are age 65 years and older average 26 prescriptions per year. The Medicare Prescription Drug Benefit final rule (published in the **Federal Register** on January 28, 2005, available online at *http://www.gpoaccess.gov*) estimates that in calendar year (CY) 2006 about 29 million Medicare beneficiaries will receive drug coverage through a Medicare Part D plan (that is, a PDP or MA–PD.) By CY 2010, with growth in the overall Medicare population, estimates indicate that about 35 million Medicare beneficiaries will be receiving this drug coverage. This impact analysis discusses the overall impact of instituting e-prescribing standards under the Medicare Prescription Drug Program. The overall requirements for supporting e-prescribing and providing incentives were discussed in the Medicare Prescription Drug Benefit proposed and final rules. However, the specific standards were not contained in that proposed rule and the impact analysis in that proposed rule did not analyze those requirements. The adoption of standards for the program will enhance the implementation and provide specific direction for providers, dispensers, plans, and vendors.

According to testimony before the NCVHS and in the written comments in response to the Medicare Prescription Drug Benefit proposed rule (69 FR 46632–46863), between 5 and 18 percent of prescribers are conducting e-prescribing.[7] However, some studies have indicated increased prescriber interest and plans to move to e-prescribing. We anticipate that the use of the standards proposed in this rule, and the fact that we are proposing that these standards be available for the January 2006 implementation of the Medicare Prescription Drug Program, will accelerate adoption of e-prescribing due to heightened awareness of the benefits, the variety of devices and connections available for prescribers, and the fact that the standards are already successfully being used. While there are no detailed models predicting specific rates of adoption for this technology, based on our sense of the likely expert consensus, we think it likely that the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next five years. The 10 percent annual growth in prescriber participation is a rough estimate, based on our expectations of—

- Publicity surrounding the Medicare Prescription Drug Program;
- More publicity about the benefits of e-prescribing and the experience of prescribers who are participating;
- Increased emphasis on health information technology in general;
- Potential cost savings to providers using e-prescribing; and
- The availability of incentives for participation.

We believe that as prescribers gain experience with e-prescribing, they will recognize the benefits and share those experiences with colleagues. We invite public comment on our expectations for prescriber participation.

[7] Howell, Investors Business Daily, September 15, 2003.

According to the Center for Information Technology Leadership (CITL), more than 8.8 million ADE occur each year in ambulatory care. E-prescribing helps to deliver relevant patient information at the time of prescribing. E-prescribing would allow a critical first level of safety checks to occur when a medication is prescribed (in addition to the patient safety software used at the point-of-service and the retrospective drug utilization reviews that are performed). The CITL estimates that nationwide adoption of e-prescribing would eliminate nearly 2.1 million ADEs per year in the U.S. This would prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening ADEs. These improvements would result in improved care and safety for health plans' members.

There is also evidence suggesting that the use of specific drugs may reduce adverse health events, utilization of other health care services, and related costs for certain groups of patients. E-prescribing would promote efficient and effective use of drugs by ensuring that prescribers have up-to-date information regarding advances in drug therapies. For example, a recent study found that the use of statins in cholesterol-lowering drug therapy reduced the incidence of coronary disease-related deaths by 24 percent in elderly men and women (ages 70 to 82) with a history of, or risk factors for, vascular disease, and also reduced the incidence of non-fatal heart attacks and fatal or non-fatal strokes in these patients (''Pravastatin in Elderly Individuals at Risk of Vascular Disease (PROSPER): A Randomised Controlled Trial,'' Lancet 2002, 360:9346, 1623–1630).

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, we believe that many elements of the Medicare prescription drug benefit, including quality assurance, better information on drug costs (for example, through generic substitution), and medication therapy management which are designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions, will be enhanced by e-prescribing. We believe that these improvements, enabled by e-prescribing programs, will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to

detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. We also believe that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescription program provisions of the MMA are implemented. (To Err is Human: Building a Safer Health System, Institute of Medicine of the National Academies, 1999, pp. 191–193, *http://www.iom.edu* or *http://www.nap.edu*.)

At this time, we cannot predict how fast all of these savings will occur, nor their precise magnitude, as they are dependent on the rate at which we are able to adopt final standards for various aspects/functions of e-prescribing, the adoption of e-prescribing by prescribers, the quality of the systems implemented for e-prescribing, and the behavioral responses of prescribers, health care practitioners, dispensers, insurers (who help manage treatments), and patients. However, as indicated by the CITL report estimate, the potential is clearly very substantial.

The ASC X12N 270/271 Transaction and the NCPDP Telecommunication Standard proposed in this rule for e-prescribing transactions, are already adopted standards for HIPAA. Thus, any costs associated with adoption of these transaction standards are already encompassed in the baseline. (The impact of implementing these standards was analyzed and adopted in the Health Insurance Reform: Standards for Electronic Transactions final rule, published on August 17, 2000 in the **Federal Register** (65 FR 50312–50372) and available on the Web through *http://www.gpoaccess.gov*.)

We note, however, that there is one very important difference between those HIPAA regulations and this proposal. In that rule, we knew that many of the electronic claims standards we were requiring were incompatible with many of those already in use for electronic billing of Medicare claims. In this proposed rule, we know that a substantial number of prescribers and other entities are already using the standards we are proposing. Thus, while the Transactions Rule and this proposed rule share common goals and methods, they have different implementation consequences.

It is important to understand that this proposed rule involves both mandatory and voluntary elements, but that even the mandatory elements are enabling. For example, the statute might have encouraged e-prescribing by making it a required condition of participation in Medicare, through positive financial incentives, by reducing barriers to adoption, by increasing the value of e-prescribing systems, or through other means. The primary method chosen by the Congress was to increase the value of e-prescribing systems by mandating uniform standards for e-prescribing. Uniform standards reduce barriers to adoption by reducing uncertainty in the marketplace regarding which standards will be the industry standards of the future. These incentives are created without imposing substantial costs. For potential new e-prescribers, whose choice to adopt e-prescribing is voluntary, these standards provide the advantages of uniformity and reduced uncertainty, and, hence, reduce costs or increase benefits of adoption. For those existing entities that currently engage in e-prescribing transactions whose systems are currently incompatible with these standards (if any), transitioning to the foundation standards will be mandatory to continue e-prescribing (with the option of returning to paper) and will come at some cost, but will also increase value of these systems in the long run as it will enable these entities to communicate with all other e-prescribers. Only for Part D sponsors is use of these standards mandatory, and even then, only to receive or reply to e-prescribing transactions initiated by other entities.

We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis. We plan to publish a more complete impact analysis in the final rule, including an assessment of impacts on the Medicare program, the effect on Part D spending, annual savings to Medicare, costs to plans and providers, and estimated costs and savings for the private sector and other Federal programs.

B. Impact on Health Plans/PBMs

The final rule on the Medicare Program Prescription Drug Benefit estimates that 100 PDP sponsors and 350 MA organizations will submit applications on an annual basis for participation in the Medicare Prescription Drug Program. Testimony presented to the NCVHS (available on the Web at *http://www.ncvhs.hhs.gov*) indicated that because most health plans/PBMs currently have e-prescribing capability, any additional costs associated with hardware/software connectivity would be minimal. Since the great majority of health plans contract with PBMs for pharmacy benefit administration, we do not consider the fees associated with these contracts to be an additional cost for plans conducting electronic prescription drug programs, although connectivity costs could increase based on volume.

Although we believe that costs incurred by health plans will be minimal, even in those few cases where plans do not currently support e-prescribing directly or through PBM contracts, it is possible that some plans will experience consequential costs that we have not foreseen. We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs. We also request comment on our expectation, discussed below, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans.

The only expense attributable to health plans by this impact analysis are those that would be incurred by plans/PBMs for voluntarily providing financial incentives and technical assistance to participating physicians to conduct e-prescribing. We expect many plans to provide these incentives to prescribers to offset prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing. We expect that this will be a transfer of costs from prescribers to health plans, and will neither increase nor decrease the overall impact of implementing an electronic prescription drug program. We note that such incentives must not and will not violate Federal or State laws prohibiting kickbacks and physician self-referrals. As stated earlier in the preamble, we will publish a proposed rule to create an exception under section 1877 of the Act, commonly called the Stark law, for incentives related to e-prescribing. Also, the Department's Inspector General is considering how best to establish a safe harbor under the Anti-Kickback Statute.

Health plans have a substantial incentive to subsidize the cost of physicians' adoption of E-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance. Thus, it is likely that the net effect on plans would be positive rather than negative. Moreover, there is no reason to expect

health plans to incur costs without the expectation of a positive return. However, we have no basis at this time for estimating the precise timing or magnitude of either gross or net savings. We request public comments and information on this topic that we can utilize when revising this analysis for the final rule.

Health plans that have offered incentives to prescribers have estimated the hardware and software costs for implementing an E-prescribing system for a provider to be approximately $1500 per prescriber. At this time, a number of health plans are developing incentive packages for prescribers to initiate e-prescribing; however, we do not have figures to indicate the extent of these offerings, and invite public comment on the impact for both prescribers and health plans. Because we cannot estimate at this time the incentives that plans may provide, we do not know how costs will be shared between prescribers and plans. Therefore, at this time we are attributing all of the costs to prescribers, as discussed in the next section.

C. Impact on Prescribers

Current surveys estimate that between 5 and 18 percent of physicians and other clinicians are using e-prescribing. According to the Agency for Healthcare Research and Quality, MEPS Highlights #11, more than 3 billion prescriptions are written annually. The ''2003 CMS Statistics'' publication reports the number of physicians in active practice at 888,061. We assume that all of these physicians are considered prescribers. However, the number of practicing physicians is not a direct measure of the volume or scope of potential e-prescribing adoption. According to the 2002 Economic Census, Health Care and Social Assistance industry publication (*http://www.census.gov*), there are about 203,000 physician office establishments. This smaller number reflects the common use of group practices and other arrangements that allow physicians to share caseload, facilities, and costs. For these and other prescribers, the likely focus of a decision to adopt e-prescribing is the office, rather than the individual physician.

Although physicians are encouraged to adopt e-prescribing technology, whether physicians prescribe electronically under the MMA is, nevertheless, voluntary. We expect e-prescribing to reduce prescriber costs and produce net economic benefits to prescribers, but the magnitude and timing of savings first will have to be demonstrated to many prescribers to induce them to make the ''up front'' investment in new systems. Finally, an additional incentive for prescribers to e-prescribe exists, which is the improved patient care that e-prescribing brings. Because we cannot determine the effect of these factors on prescribers at this time, we do not know how many prescribers will move to e-prescribing or when they will do so.

After this proposed rule becomes final, once a prescriber decides to conduct e-prescribing for Part D drugs, for Part D enrolled beneficiaries, the prescriber would be required to comply with the standards being proposed in this regulation. However, we have no reason to believe that the use of these particular proposed standards would increase costs for new adopters, compared to what costs otherwise would have been. Even for those (and we think they are few) who are currently using systems that may be in some respects incompatible with these standards, we would expect vendors to upgrade those systems at no or nominal cost as part of their normal version updating process. Moreover, a system that uses uniform standards would enable a prescriber to do business with multiple entities, and reduce costs compared to the alternative of having to deal with multiple conflicting systems. We do, however, request comments on whether there are some transition costs attributable to these standards and whether there are steps that we could take to mitigate those costs.

One of the barriers to early adoption of e-prescribing by prescribers is the cost of buying and installing a system. Included in the overall costs of buying and installing systems are several factors including—

- Changing in the business practices of providers' offices.
- Changing record systems from paper to electronic; and
- Training staff.

Since these costs may be defrayed by the incentives that are being offered, or that may be offered, to prescribers, we expect a steady increase in the number electronic prescribers. We do not know all of the various incentives being offered, but are aware that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees (as indicated above, such arrangements must not violate Federal and State laws prohibiting kickbacks and physician self-referrals). We invite public comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or likely to be offered subsequent to the publishing of regulations to create an exception to the Stark law and an anti-kickback safe harbor for e-prescribing. We also anticipate that increased communication regarding the safety improvements and cost savings experienced with e-prescribing will encourage prescriber acceptance.

There is anecdotal evidence of direct economic benefits that accrue to prescribers that implement e-prescribing, in addition to the previously discussed health benefits to patients. The following examples of these benefits have been reported:

- A 53 percent reduction in calls from, and a 62 percent reduction in calls to, the pharmacy.
- Time savings of one hour per nurse and 30 minutes per file clerk per day by streamlining medication management processes.
- A large practice in Lexington, Kentucky estimates that e-prescribing saves the group $48,000 a year in decreased time spent handling prescription renewal requests.
- Prior to implementation of e-prescribing, a large practice in Kokomo, Indiana with 20 providers and 134,000 annual patient office visits was receiving 370 daily phone calls, 206 of which were related to prescriptions. Of the 206 prescription-related calls, 97 were prescription renewal requests. The remainder consisted of clarification calls from pharmacists or requests for new prescriptions. Staff time to process these calls included 28 hours per day of nurse time and 4 hours per day of physician time. Chart pulls were required in order to process half of the renewal requests. Implementation of an e-prescribing system produced dramatic time savings that permitted reallocation of nursing and chart room staff.
- Potential reductions in malpractice insurance because of improvements in the quality of patient care resulting from better tracking of patients' drug regimen and a reduction of ADEs, which may occur with e-prescribing.

These examples come from large practices, but we would expect that most if not all of them would apply equally well to smaller practices. We request public comments and additional information on actual and potential savings, particularly in solo and small group practices.

As can be seen from this discussion, there are both potential costs and potential benefits for providers that implement e-prescribing. The number of prescriptions that a provider writes is a critical issue for providers in determining whether an e-prescribing system will be cost beneficial to them. Although a cost of approximately $1500,

amortized over several years, would appear very small in the context of even a solo practitioner's overall practice costs (and certainly far below the threshold of 3 to 5 percent of revenues that we normally use for economic significance determinations under the RFA), it is possible that some providers may be negatively affected. However, the voluntary nature of e-prescribing for prescribers makes this unlikely, since each is free to make its own business decision regarding whether and how to implement e-prescribing. Prescribers that have already implemented e-prescribing are also unlikely to be negatively affected, because the standards we are proposing are currently used by most e-prescribing software products in use.

At this time we do not have sufficient information on either the costs or benefits for a given type or size of provider to conduct a cost-benefit analysis for that provider type or size. We are requesting information on these factors to help us improve our analysis for the final rule. Additional examples of administrative savings from e-prescribing, as well as costs of implementing such systems, would be particularly beneficial.

D. Impact on Pharmacies and Other Dispensers

Testimony from pharmacists and professional pharmacy organizations provided to the NCVHS (available on the Web at *http://www.ncvhs.hhs.gov*) reported the following benefits of e-prescribing for pharmacies:

- Reduced time-consuming phone calls to physicians.
- Improved accuracy and less time for refill authorizations.
- Additional time available for patient contact and services.
- Improved prescription communication between prescriber and dispenser (through, among other things, reduction in illegible handwritten paper prescriptions).
- Improved turnaround time for refill authorizations.

We do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing. While we expect to see the efficiencies (discussed at the beginning of this section) at pharmacies with some possible reductions in administrative staff time, we do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program. The industry has provided information indicating that 75 percent [8] of the 57,208 pharmacies [9] in the U.S. already have e-prescribing capability which suggests that pharmacies already find this a beneficial investment. In this respect, we note that the great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small. For example, as indicated earlier in this preamble, we believe that over 95 percent of pharmacy systems are already compatible with the NCPDP retail pharmacy drug claim standard. Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.

E. Impact on Patients

E-prescribing has the potential for improving beneficiary health outcomes. E-prescribing systems enable appropriate drug compliance management and improved medication use, and provide information to prevent adverse drug events. E-prescribing systems can improve patient safety by detecting various kinds of prescribing errors, including duplicate prescriptions; drug-drug, drug-allergy and drug-disease interactions; incorrect dosage strengths prescribed; and problems relating to coordination between health care providers and pharmacies. These reductions in errors and improvements in regimens would occur over time as more and more providers use the e-prescribing systems for the Medicare Prescription Drug Benefit.[10] E-prescribing can also drive physicians to appropriate formulary choices, which can save money for the health plans, patients, and health care system.

Nothing in this system creates direct costs for patients. We believe that reductions in patient mortality and morbidity would be a substantial benefit resulting from the adoption of e-prescribing, although we are unable at this time to provide quantitative estimates. Patient health benefits are likely to far exceed the other categories of benefits and direct costs.

[8] Hutchinson, Kevin, SureScripts. Testimony before the NCVHS Subcommittee on Standards and Security, May 25, 2004.

[9] National Community Pharmacists' Association, press release, June 29, 2004.

[10] To Err is Human: Building a Safer Health System, Institute of Medicine of the National Academies, 1999, pp. 191–193, *http://www.oim.edu* or *http://www.nap.edu*.

F. Impact on Others

We see the growth of e-prescribing as business potential for healthcare information technology vendors. Any costs associated with e-prescribing and potential business opportunities could be allocated toward new product development. We have no estimates for these types of costs, and invite public comment from healthcare information technology vendors and others on the impact of e-prescribing.

E-prescribing is in widespread use among some segments of the industry such as pharmacies and PBMs; however, we have not determined the impact and extent of experience for other entities such as pharmaceutical and medical device manufacturers, public health organizations, research and academic institutions, and professional lay organizations. We invite public comment on the impact of e-prescribing for these entities. The Health Information Network Weekly Update (Volume VI, No. 49, November 15, 2004) stated that e-prescribing is at the top of the list of e-health applications that will see the greatest growth. Thirty-nine percent of participants predict e-prescribing will be the most widely embraced e-health application.

G. Impact on Small Businesses

The RFA requires agencies to analyze options for regulatory relief for small businesses when proposed rules may create a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $6 million a year. For purposes of the RFA, approximately 95 percent of pharmacy firms, which account for about 51 percent of pharmacy establishments, are small business based upon 1997 Census data. There are 57,208 retail pharmacy establishments based upon ''2004 National Community Pharmacists Association Pfizer Digest.'' Therefore, we estimate that more than 29,000 pharmacy establishments would be considered small entities. Almost all physicians in private practice (or the practices of which they are members) are small entities because their annual revenues do not meet the Small Business Administration's $8.5 million threshold for ''small'' physician practices. Individuals and States are not included in the definition of a small entity, and this proposed rule has no

effect on small governmental jurisdictions.

We believe that this proposed rule would have an impact on a substantial number of small businesses due to the percentage of pharmacies and providers that are small businesses. We recognize that there will be a distribution of costs and benefits with proportionately higher costs incurred by smaller entities than by larger entities, primarily as a result of economies of scale. However, as indicated earlier in this section, as many as 75 percent of pharmacies already are conducting e-prescribing and 5 to 18 percent of prescribers are using this technology. Clearly, these rates of voluntary adoption indicate that it provides net economic benefits. Furthermore, this proposed rule recognizes that e-prescribing remains voluntary for entities that are not Part D sponsors. That is, prescribers and dispensers are only required to comply with the standards under section 1850D–4(e)(1) of the Act if they electronically transmit prescriptions or other information, with respect to Part D drugs for beneficiaries enrolled in Part D. Finally, we believe that the effects of adoption are economically beneficial to affected entities.

We note that this conclusion differs from the impact of the HIPAA Transactions Rule. The HIPAA Transactions Rule, although voluntary for health care providers, was determined to have a significant impact. The basis for that determination was that a significant percentage of providers were already conducting the relevant transactions electronically in nonstandard form. For example, over 80 percent of Medicare claims submitted by physicians were transmitted electronically. Those providers would have been required to switch to the HIPAA standards, which were not in widespread use, creating a burden on a large percentage of affected entities. By contrast, only 5 to 18 percent of prescriptions are conducted electronically, and the small number of providers who are doing so are very likely already using the standards we are proposing.

Accordingly, we conclude that this proposed rule would not have a significant economic impact upon a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required. We welcome comments on this conclusion and additional information on the small business effects of this proposed rule.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the standards of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This proposed rule would not affect small rural hospitals because the program will be directed at outpatient prescription drugs and not drugs provided during a hospital stay. Prescription drugs provided during hospital stays are covered under Medicare as part of Medicare payments to hospitals. Therefore, we are not providing an analysis. We further estimate that this proposed rule would not have a significant impact on small rural hospitals because the e-prescribing provisions are both voluntary and cost-beneficial for prescribers. In-hospital pharmacy units and staff physicians should face the same benefit/cost calculus as their counterparts, and would, therefore, have no net costs imposed upon them by adoption of e-prescribing.

H. Effects on States and Federalism Statement

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. The private sector would incur costs for hardware and software upgrades, and connectivity for implementation of e-prescribing. However, except for MA and PDP plans, this proposed rule does not include any mandate that would result in this spending because it only deals with the informational standards to be used in voluntarily adopted practices, and, therefore, that spending does not pertain to the thresholds of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Furthermore, we believe that the effects of adoption will be positive, rather than involve net expenditures. Regardless, even using our estimates of significant increases in the use of e-prescribing, we do not believe annual expenditures on installing this capability will reach $110 million annually. Certainly, we would expect the only entities that are required to comply, Part D sponsors (and possibly a few existing e-prescribers), to incur only minimal costs, totaling no more than a small fraction of this threshold.

With respect to States, nothing in this proposed rule mandates any expenditure by States. While some hospitals and other providers are State-owned, our conclusions with respect to each type of affected entity are not affected by ownership status.

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 costs on State and local governments, preempts State law, or otherwise has Federalism implications. For the same reasons given above, we have determined that States would not incur any direct costs as a result of this proposed rule. However, as discussed previously in this preamble, and as mandated by section 1860D–4(e) of the Act, we are proposing to preempt State law. Under the Executive Order, we are required to minimize the extent of preemption, consistent with achieving the objectives of the Federal statute, and to meet certain other conditions. We believe that, taken as a whole, this proposed rule would meet these requirements. We do seek comments from States and other entities on possible problems and on ways to minimize conflicts, consistent with achieving the objectives of the MMA, and will be undertaking outreach to States on these issues.

We have consulted with the National Association of Boards of Pharmacy directly and through participation in NCVHS hearings, and we believe that the approach we suggest as to the scope of preemption discussed earlier in the preamble provide both States and other affected entities the best possible means of addressing preemption issues. We will consult further with States before issuing the final rule. This section, together with the earlier preamble section entitled ''State Preemption'', constitute the Federalism summary impact statement required under the Executive Order.

I. Conclusion and Alternatives Considered

For the reasons given above, we are not preparing analyses under the RFA, section 1102(b) of the Act, or the Unfunded Mandates Reform Act. We have, nevertheless, considered the alternatives discussed below. We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.

Two sets of standards that we are proposing in this rule already are required standards under the Administrative Simplification provisions of HIPAA. The ASC X12N

270/271—Health Care Eligibility Benefit Inquiry and Response and NCPDP Telecommunication Standard are adopted standards and required when conducting standard transactions. We are proposing these standards for e-prescribing because they are already adopted standards for HIPAA transactions and meet some of the requirements specified in Title I, section 1860D–4(e) of the Act, as amended by section 101 of the MMA.

The NCPDP SCRIPT Standard is in widespread use and meets many of the e-prescribing requirements outlined in section 1860D–4(e) of the Act. Also, NCPDP is developing NCPDP SCRIPT transactions to meet other MMA requirements for future consideration or pilot testing. The NCVHS did not recommend any viable alternatives for e-prescribing foundation standards because testimony presented by the industry during the NCVHS hearings strongly supported the NCPDP SCRIPT Standard (available on the Web at *http://www.ncvhs.hhs.gov*).

An alternative to adopting these particular standards as final foundation standards for e-prescribing would be to pilot test the recommended standards. The NCVHS did not recommend pilot testing for these foundation standards because they are already adopted standards with adequate industry experience.

Another alternative considered would be to adopt formulary and medical history standards based on proprietary standards that are not ANSI accredited. If the coalition developing these standards is successful with the accreditation process and there is evidence of adequate industry experience with these standards, the standards could be adopted in the final rule. We would consider including a functional equivalence standard in the final rule if a reasonable one could be devised. However, the standards proposed allow alternatives, as long as the informational content and format are comparable.

List of Subjects 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations, (HMO), Health professions, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For reasons set forth in the preamble in this proposed regulation, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 423 (to be published on January 28, 2005 and effective on March 22, 2005) as follows:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

1. The authority citation for Part 423 continues to read as follows:

Authority: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart D—Cost Control and Quality Improvement Requirements

2. The title for subpart D is revised to read as set forth above.

3. In § 423.150, paragraph (c) is revised to read as follows:

§ 423.150 Scope.

* * * * *

(c) Electronic prescription drug programs for prescribers, dispensers and Part D sponsors.

* * * * *

4. Section 423.159 is amended by revising the heading and adding a new paragraph (a) to read as follows:

§ 423.159 Electronic Prescription Drug Program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Dispenser means a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice.

Electronic media shall have the same meaning as this term is defined in 45 CFR 160.103.

E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network.

Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan.

* * * * *

5. Section 423.160 is added to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) *General Rules.* (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals enrolled in a Part D plan.

(2) Prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals enrolled in a Part D plan.

(b) *Standards.* (1) Prescription. The National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12, 2004, to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(i) Get message transaction.

(ii) Status response transaction.

(iii) Error response transaction.

(iv) New prescription transaction.

(v) Prescription change request transaction.

(vi) Prescription change response transaction.

(vii) Refill prescription request transaction.

(viii) Refill prescription response transaction.

(ix) Verification transaction.

(x) Password change transaction.

(xi) Cancel prescription request transaction.

(xii) Cancel prescription response transaction.

(2) Eligibility. (i) The American Standards Committee X12N 270/271–Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.

(ii) The National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP

Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record, for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

(c) *Incorporation by reference.* The Director of the Federal Register approves, in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51, the incorporation by reference of the National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12, 2004, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill); the American Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, and the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. You may inspect copies of these materials at the headquarters of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. or at the National Archives and Records Administration (NARA). For information on the availability of this material at CMS, call 410–786–0273. For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* You may obtain a copy of the National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12, 2004, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and FAX (480) 767–1042 or *http://www.ncpdp.org.* You may obtain a copy of the American Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 from the Washington Publishing Company, PMB 161, 5284 Randolph Road, Rockville, MD, 20852–2116; Telephone (301) 949–9740; and FAX: (301) 949–9742 or *http://www.wpc-edi.com/.* You may obtain a copy of the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and FAX (480) 767–1042 or *http://www.ncpdp.org.*

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 4, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 12, 2005.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–1773 Filed 1–27–05; 11:04 am]

BILLING CODE 4120–01–P

Federal Register

Friday,
February 4, 2005

Part VI

Department of Housing and Urban Development

Federal Property Suitable as Facilities To Assist the Homeless; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4980–N–05]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, room 7266, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to John Hicks, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: ARMY: Ms. Audrey C. Ormerod, Headquarters, Department of the Army, Office of the Assistant Chief of Staff for Installation Management, Attn: DAIM–MD, 600 Army Pentagon, Washington, DC 20310–0600; (703) 601–2520; (These are not toll-free numbers).

Dated: January 27, 2005.

Mark R. Johnston,

Director, Office of Special Needs Assistance Programs.

Title V, Federal Surplus Property Program Federal Register Report for 2/4/05

Suitable/Available Properties

Buildings (by State)

Alaska

Armory
NG Noorvik
Noorvik AK 99763–
Landholding Agency: Army
Property Number: 21200110075
Status: Unutilized
Comment: 1200 sq. ft., most recent use—armory, off-site use only

Bldg. 00001
Kiana Natl Guard Armory
Kiana AK 99749–
Landholding Agency: Army
Property Number: 21200340075
Status: Excess
Comment: 1200 sq. ft., butler bldg., needs repair, off-site use only

Arizona

Bldg. 30012, Fort Huachuca
Sierra Vista Co: Cochise AZ 85635–
Landholding Agency: Army
Property Number: 21199310298
Status: Excess
Comment: 237 sq. ft., 1-story block, most recent use—storage

Bldg. S–306
Yuma Proving Ground
Yuma Co: Yuma/La Paz AZ 85365–9104
Landholding Agency: Army
Property Number: 21199420346
Status: Unutilized
Comment: 4103 sq. ft., 2-story, needs major rehab, off-site use only

Bldg. 503, Yuma Proving Ground
Yuma Co: Yuma AZ 85365–9104
Landholding Agency: Army
Property Number: 21199520073
Status: Underutilized
Comment: 3789 sq. ft., 2-story, major structural changes required to meet floor loading & fire code requirements, presence of asbestos, off-site use only

Bldg. 00500
Yuma Proving Ground
Yuma AZ 85365–9498
Landholding Agency: Army
Property Number: 21200340076
Status: Unutilized
Comment: 4171 sq. ft., needs rehab, possible asbestos/lead paint, mostrecent use—training, off-site use only

Bldg. 43002
Fort Huachuca
Cochise Co: AZ 85613–7010
Landholding Agency: Army
Property Number: 21200440066
Status: Excess
Comment: 23,152 sq. ft., presence of asbestos/lead paint, most recent use—dining, off-site use only

California

Bldgs. 18026, 18028
Camp Roberts
Monterey CA 93451–5000
Landholding Agency: Army
Property Number: 21200130081
Status: Excess
Comment: 2024 sq. ft. & 487 sq. ft., concrete, poor condition, off-site use only

Colorado

Bldg. T–108
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200130083
Status: Unutilized
Comment: 9000 sq. ft., poor condition, possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–209
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency Army
Property Number: 21200130084
Status: Unutilized
Comment: 400 sq. ft., poor condition, possible asbestos/lead paint, most recent use—maint. shop, off-site use only

Bldg. T–217
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200130085
Status: Unutilized
Comment: 9000 sq. ft., poor condition, possible asbestos/lead paint, most recent use—maint., off-site use only

Bldg. T–218
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency Army
Property Number: 21200130086
Status: Unutilized
Comment: 9000 sq. ft., poor condition, possible asbestos/lead paint, most recent use—maint., off-site use only

Bldg. T–220
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200130087
Status: Unutilized
Comment: 690 sq. ft., poor condition, possible asbestos/lead paint, most recent use—heat plant, off-site use only

Bldg. T–6001
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200130088
Status: Unutilized
Comment: 4372 sq. ft., poor condition, possible asbestos/lead paint, most recent use—vet clinic, off-site use only

Bldg. S6263
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200310051
Status: Unutilized
Comment: 24,902 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—offices, off-site use only

Bldg. T–211
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200340080
Status: Unutilized
Comment: 4172 sq. ft., presence of asbestos/lead paint, most recent use—office, off-site use only

Bldg. S6268
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200340085
Status: Unutilized
Comment: 840 sq. ft., presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. 25, 26, 27 Pueblo Chemical Depot
Pueblo CO 81006–
Landholding Agency: Army
Property Number: 21200420178
Status: Unutilized Comment: 1311 sq. ft., presence of asbestos/lead paint, most recent use—housing, off-site use only

Bldg. 00127
Pueblo Chemical Depot
Pueblo CO 81006–
Landholding Agency: Army
Property Number: 21200420179
Status: Unutilized
Comment: 8067 sq. ft., presence of asbestos, most recent use—barracks, off-site use only

Georgia

Bldg. 1252, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220694
Status: Unutilized
Comment: 583 sq. ft., 1 story, most recent use—storehouse, needs major rehab, off-site removal only.

Bldg. 4963, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220710
Status: Unutilized
Comment: 6077 sq. ft., 1 story, most recent use—storehouse, need repairs, off-site removal only.

Bldg. 2396, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220712
Status: Unutilized
Comment: 9786 sq. ft., 1 story, most recent use—dining facility, needs major rehab, off-site removal only.

Bldg. 4882, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220727
Status: Unutilized
Comment: 6077 sq. ft., 1 story, most recent use—storage, need repairs, off–site removal only

Bldg. 4967, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220728
Status: Unutilized
Comment: 6077 sq. ft., 1 story, most recent use—storage, need repairs, off-site removal only

Bldg. 4977, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220736
Status: Unutilized
Comment: 192 sq. ft., 1 story, most recent use—offices, need repairs, off-site removal only

Bldg. 4944,
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220747
Status: Unutilized
Comment: 6400 sq. ft., 1 story, most recent use—vehicle maintenance shop, need repairs, off-site removal only

Bldg. 4884, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220762
Status: Unutilized
Comment: 2000 sq. ft., 1 story, most recent use—headquarters bldg., need repairs, off-site removal only

Bldg. 4964, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220763
Status: Unutilized
Comment: 2000 sq. ft., 1 story, most recent use—headquarters bldg., need repairs, off-site removal only

Bldg. 4966, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220764
Status: Unutilized
Comment: 2000 sq. ft., 1 story, most recent use—headquarters bldg., need repairs, off-site removal only

Bldg. 4965, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220769
Status: Unutilized
Comment: 7713 sq. ft., 1 story, most recent use—supply bldg., need repairs, off-site removal only

Bldg. 4945, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199220779
Status: Unutilized
Comment: 220 sq. ft., 1 story, most recent use—gas station, needs major rehab, off-site removal only

Bldg. 4023, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199310461
Status: Unutilized
Comment: 2269 sq. ft., 1-story, needs rehab, most recent use—maintenance shop, off-site use only

Bldg. 4024, Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199310462
Status: Unutilized
Comment: 3281 sq. ft., 1-story, needs rehab, most recent use—maintenance shop, off-site use only

Bldg 4051, Fort Benning
Ft. Benning Co: Muscogee GA 31905–

Landholding Agency: Army
Property Number: 21199520175
Status: Unutilized
Comment: 967 sq. ft., 1-story, needs rehab, most recent use—storage, off-site use only

Bldg. 322
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199720156
Status: Unutilized
Comment: 9600 sq. ft., needs rehab, most recent use—admin., off-site use only

Bldg. 2593
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199720167
Status: Unutilized
Comment: 13644 sq. ft., needs rehab, most recent use—parachute shop, off-site use only

Bldg. 2595
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199720168
Status: Unutilized
Comment: 3356 sq. ft., needs rehab, most recent use—chapel, off-site use only

Bldg. 4476
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199720184
Status: Unutilized
Comment: 3148 sq. ft., needs rehab, most recent use—vehicle maint. shop, off-site use only

Bldg. 92
Fort Benning
Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199830278
Status: Unutilized
Comment: 637 sq. ft., needs rehab, most recent use—admin., off-site use only

Bldg. 4232
Fort Benning
Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199830291
Status: Unutilized
Comment: 3720 sq. ft., needs rehab, most recent use—maint. bay, off-site use only

Bldg. 39720
Fort Gordon
Ft. Gordon Co: Richmond GA 30905–
Landholding Agency: Army
Property Number: 21199930119
Status: Unutilized
Comment: 1520 sq. ft., concrete block, possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. 1370
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930122
Status: Unutilized
Comment: 5204 sq. ft., most recent use—hdqts. bldg., off-site use only

Bldg. 2288
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930123
Status: Unutilized
Comment: 2481 sq. ft., most recent use—admin., off-site use only

Bldg. 2293
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930125
Status: Unutilized
Comment: 2600 sq. ft., most recent use—hdqts. bldg., off-site use only

Bldg. 2297
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930126
Status: Unutilized
Comment: 5156 sq. ft., most recent use—admin.

Bldg. 2508
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930128
Status: Unutilized
Comment: 2434 sq. ft., most recent use—storage, off-site use only

Bldg. 2815
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930129
Status: Unutilized
Comment: 2578 sq. ft., most recent use—hdqts. bldg., off-site use only

Bldg. 3815
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930130
Status: Unutilized
Comment: 7575 sq. ft., most recent use—storage, off-site use only

Bldg. 3816
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930131
Status: Unutilized
Comment: 7514 sq. ft., most recent use—storage, off-site use only

Bldg. 5886
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930134
Status: Unutilized
Comment: 67 sq. ft., most recent use—maint/storage, off-site use only

Bldgs. 5974–5978
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930135
Status: Unutilized
Comment: 400 sq. ft., most recent use—storage, off-site use only

Bldg. 5993
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930136
Status: Unutilized
Comment: 960 sq. ft., most recent use—storage, off-site use only

Bldg. 5994
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199930137
Status: Unutilized
Comment: 2016 sq. ft., most recent use—storage, off-site use only

Bldg. T–1003
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030085
Status: Excess
Comment: 9267 sq. ft., poor condition, most recent use—admin., off-site use only

Bldgs. T–1005, T–1006, T–1007
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030086
Status: Excess
Comment: 9267 sq. ft., poor condition, most recent use—storage, off-site use only

Bldgs. T–1015, T–1016, T–1017
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030087
Status: Excess
Comment: 7496 sq ft., poor condition, most recent use—storage, off-site use only

Bldgs. T–1018, T–1019
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030088
Status: Excess
Comment: 9267 sq. ft., poor condition, most recent use—storage, off-site use only

Bldgs. T–1020, T–1021
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030089
Status: Excess
Comment: 9267 sq. ft., poor condition, most recent use—storage, off-site use only

Bldg. T–1022
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030090
Status: Excess
Comment: 9267 sq. ft., poor condition, most recent use—supply center, off-site use only

Bldg. T–1027
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030091
Status: Excess
Comment: 9024 sq ft., poor condition, most recent use—storage, off-site use only

Bldg. T–1028
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030092
Status: Excess

Comment: 7496 sq. ft., poor condition, most recent use—storage, off-site use only

Bldgs. T–1035, T–1036, T–1037
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030093
Status: Excess
Comment: 1626 sq ft., poor condition, most recent use—storage, off-site use only

Bldgs. T–1038, T–1039
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030094
Status: Excess
Comment: 1626 sq. ft., poor condition, most recent use—storage, off-site use only

Bldgs. T–1040, T–1042
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030095
Status: Excess
Comment: 1626 sq. ft., poor condition, most recent use—storage, off-site use only

Bldgs. T–1086, T–1087, T–1088
Fort Stewart
Hinesville Co: Liberty GA 31514–
Landholding Agency: Army
Property Number: 21200030096
Status: Excess
Comment: 7680 sq. ft., poor condition, most recent use—storage, off-site use only

Bldg. T0130
Fort Stewart
Hinesville Co: Liberty GA 31314–5136
Landholding Agency: Army
Property Number: 21200230041
Status: Excess
Comment: 10,813 sq. ft., off-site use only

Bldg. T0157
Fort Stewart
Hinesville Co: Liberty GA 31314–5136
Landholding Agency: Army
Property Number: 21200230042
Status: Excess
Comment: 1440 sq. ft., off-site use only

Bldg. T0251
Fort Stewart
Hinesville Co: Liberty GA 31314–5136
Landholding Agency: Army
Property Number: 21200230043
Status: Excess
Comment: 27,254 sq. ft., off-site use only

Bldgs. T291, T292
Fort Stewart
Hinesville Co: Liberty GA 31314–5136
Landholding Agency: Army
Property Number: 21200230044
Status: Excess
Comment: 5220 sq. ft. each, off-site use only

Bldg. T0295
Fort Stewart
Hinesville Co: Liberty GA 31314–5136
Landholding Agency: Army
Property Number: 21200230045
Status: Excess
Comment: 5220 sq. ft., off-site use only

Bldg. T0470
Fort Stewart
Hinesville Co: Liberty GA 31314–5136
Landholding Agency: Army
Property Number: 21200230046
Status: Excess
Comment: 27,254 sq. ft., off-site use only

Bldg. T1191
Fort Stewart
Hinesville Co: Liberty GA 31314–5136
Landholding Agency: Army
Property Number: 21200230047
Status: Excess
Comment: 9386 sq. ft., off-site use only

Bldg. T1192
Fort Stewart
Hinesville Co: Liberty GA 31314–5136
Landholding Agency: Army
Property Number: 21200230048
Status: Excess
Comment: 3992 sq. ft., off-site use only

Bldgs. 00064, 00065
Camp Frank D. Merrill
Dahlonega Co: Lumpkin GA 30597–
Landholding Agency: Army
Property Number: 21200330108
Status: Unutilized
Comment: 648 sq. ft. each, concrete block, most recent use—water support treatment bldg., off-site use only

Bldg. 00232
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420007
Status: Excess
Comment: 2436 sq. ft., most recent use—headquarters bldg., off-site use only

Bldg. P1450
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420027
Status: Excess
Comment: 100,230 sq. ft., most recent use—health clinic, off-site use only

Bldg. 4151
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420032
Status: Excess
Comment: 3169 sq. ft., most recent use—battle lab, off-site use only

Bldg. 4152
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420033
Status: Excess
Comment: 721 sq. ft., most recent use—battle lab, off-site use only

Bldg. 4476
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420034
Status: Excess
Comment: 3148 sq. ft., most recent use—veh. maint. shop, off-site use only

Bldg. 8771
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420044
Status: Excess
Comment: 972 sq. ft., most recent use—RH/TGT house, off-site use only

Bldg. 9028
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420049
Status: Excess
Comment: 54 sq. ft., most recent use—sew/wst wtr treatment, off-site use only

Bldg. 9029
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420050
Status: Excess
Comment: 7356 sq. ft., most recent use—heat plant bldg., off-site use only

Bldg. 11370
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420051
Status: Excess
Comment: 9602 sq. ft., most recent use—nco/enl bldg., off-site use only

Bldg. T924
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420194
Status: Excess
Comment: 9360 sq. ft., most recent use—warehouse, off-site use only

Hawaii

P–88
Aliamanu Military Reservation
Honolulu Co: Honolulu HI 96818–
Location: Approximately 600 feet from Main Gate on Aliamanu Drive.
Landholding Agency: Army
Property Number: 21199030324
Status: Unutilized
Comment: 45,216 sq. ft. underground tunnel complex, pres. of asbestos clean-up required of contamination, use of respirator required by those entering property, use limitations

Bldg. T–337
Fort Shafter
Honolulu Co: Honolulu HI 96819–
Landholding Agency: Army
Property Number: 21199640203
Status: Unutilized
Comment: 132 sq. ft., most recent use—storage, off-site use only

Bldg. 06508
Schofield Barracks
Wahiawa HI 96786–
Landholding Agency: Army
Property Number: 21200220106
Status: Unutilized
Comment: 1140 sq. ft., most recent use—office, off-site use only

Illinois

Bldg. 54
Rock Island Arsenal
Rock Island Co: Rock Island IL 61299–
Landholding Agency: Army
Property Number: 21199620666
Status: Unutilized
Comment: 2000 sq. ft., most recent use—oil storage, needs repair, off-site use only

Bldg. AR112
Sheridan Reserve
Arlington Heights IL 60052–2475
Landholding Agency: Army

Property Number: 21200110081
Status: Unutilized
Comment: 1000 sq. ft., off-site use only

Louisiana

Bldg. 8423, Fort Polk
Ft. Polk Co: Vernon Parish LA 71459–
Landholding Agency: Army
Property Number: 21199640528
Status: Underutilized
Comment: 4172 sq. ft., most recent use—barracks

Maryland

Bldg. 0459B
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120106
Status: Unutilized
Comment: 225 sq. ft., poor condition, most recent use—equipment bldg., off-site use only

Bldg. 00785
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120107
Status: Unutilized
Comment: 160 sq. ft., poor condition, most recent use—shelter, off-site use only

Bldg. E3728
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120109
Status: Unutilized
Comment: 2596 sq. ft., presence of asbestos/lead paint, most recent use—testing facility, off-site use only

Bldg. E5239
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120113
Status: Unutilized
Comment: 230 sq. ft., most recent use—storage, off-site use only

Bldg. E5317
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120114
Status: Unutilized
Comment: 3158 sq. ft., presence of asbestos/lead paint, most recent use—lab, off-site use only

Bldg. E5637
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120115
Status: Unutilized
Comment: 312 sq. ft., presence of asbestos/lead paint, most recent use—lab, off-site use only

Bldg. 219
Ft. George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 21200140078
Status: Unutilized
Comment: 8142 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 294
Ft. George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 21200140081
Status: Unutilized
Comment: 3148 sq. ft., presence of asbestos/lead paint, most recent use—entomology facility, off-site use only

Bldg. 949
Ft. George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 21200140083
Status: Unutilized
Comment: 2441 sq. ft., presence of asbestos/lead paint, most recent use—storehouse, off-site use only

Bldg. 979
Ft. George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 21200140084
Status: Unutilized
Comment: 2331 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 1007
Ft. George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 21200140085
Status: Unutilized
Comment: 3108 sq. ft., presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 02207
Fort Meade
Ft. Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 21200220112
Status: Unutilized
Comment: 6855 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 2214
Fort George G. Meade
Fort Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 21200230054
Status: Unutilized
Comment: 7740 sq. ft., needs rehab, possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 00375
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320107
Status: Unutilized
Comment: 64 sq. ft., most recent use—storage, off-site use only

Bldg. 0385A
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320110
Status: Unutilized
Comment: 944 sq. ft., off-site use only

Bldg. 00523
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320113
Status: Unutilized
Comment: 3897 sq. ft., most recent use—paint shop, off-site use only

Bldg. 00649
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320116
Status: Unutilized
Comment: 1079 sq. ft., most recent use—storage, off-site use only

Bldg. 00657
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320119
Status: Unutilized
Comment: 1048 sq. ft., most recent use—bunker, off-site use only

Bldg. 0700B
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320121
Status: Unutilized
Comment: 505 sq. ft., off-site use only

Bldg. 01113
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320128
Status: Unutilized
Comment: 1012 sq. ft., off-site use only

Bldgs. 01124, 01132
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320129
Status: Unutilized
Comment: 740/2448 sq. ft., most recent use—lab, off-site use only

Bldgs. 02373, 02378
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320130
Status: Unutilized
Comment: 8359 sq. ft., most recent use—training, off-site use only

Bldg. 03558
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320133
Status: Unutilized
Comment: 18,000 sq. ft., most recent use—storage, off-site use only

Bldg. 05262
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320136
Status: Unutilized
Comment: 864 sq. ft., most recent use—storage, off-site use only

Bldg. 05608
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320137
Status: Unutilized
Comment: 1100 sq. ft., most recent use—maint bldg., off-site use only

Bldg. E5108
Aberdeen Proving Grounds

Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320147
Status: Unutilized
Comment: 5155 sq. ft., most recent use—recreation center, off-site use only

Bldg. E5483
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320148
Status: Unutilized
Comment: 2140 sq. ft., most recent use—vehicle storage, off-site use only

Bldg. E5645
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200320150
Status: Unutilized
Comment: 548 sq. ft., most recent use—storage, off-site use only

Bldg. 00435
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330111
Status: Unutilized
Comment: 1191 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. 0449A
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330112
Status: Unutilized
Comment: 143 sq. ft., needs rehab, most recent use—substation switch bldg., off-site use only

Bldg. 0460
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330114
Status: Unutilized
Comment: 1800 sq. ft., needs rehab, most recent use—electrical EQ bldg., off-site use only

Bldg. 00914
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330118
Status: Unutilized
Comment: needs rehab, most recent use—safety shelter, off-site use only

Bldg. 00915
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330119
Status: Unutilized
Comment: 247 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. 01189
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330126
Status: Unutilized
Comment: 800 sq. ft., needs rehab, most recent use—range bldg., off-site use only

Bldg. E1413
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330127
Status: Unutilized
Comment: needs rehab, most recent use—observation tower, off-site use only

Bldg. E2350A
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330132
Status: Unutilized
Comment: 325 sq. ft., need rehab, most recent use—oil storage, off-site use only

Bldg. 2456
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330133
Status: Unutilized
Comment: 4720 sq. ft., needs rehab, presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. E3175
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330134
Status: Unutilized
Comment: 1296 sq. ft., needs rehab, most recent use—hazard bldg., off-site use only

4 Bldgs.
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Location: E3224, E3228, E3230, E3232, E3234
Landholding Agency: Army
Property Number: 21200330135
Status: Unutilized
Comment: sq. ft. varies, needs rehab, most recent use—lab test bldgs., off-site use only

Bldg. E3241
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330136
Status: Unutilized
Comment: 592 sq. ft., needs rehab, most recent use—medical res bldg., off-site use only

Bldgs. E3269, E3270
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330138
Status: Unutilized
Comment: 200/1200 sq. ft., needs rehab, most recent use—flam. storage, off-site use only

Bldg. E3300
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330139
Status: Unutilized
Comment: 44,352 sq. ft., needs rehab, most recent use—chemistry lab, off-site use only

Bldg. E3335
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330144
Status: Unutilized
Comment: 400 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldgs. E3360, E3362, E3464
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330145
Status: Unutilized
Comment: 3588/236 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. E3542
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330148
Status: Unutilized
Comment: 1146 sq. ft., needs rehab, most recent use—lab test bldg., off-site use only

Bldgs. 03554, 03556
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330149
Status: Unutilized
Comment: 18,000/9,000 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. E4420
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330151
Status: Unutilized
Comment: 14,997 sq. ft., needs rehab, most recent use—police bldg., off-site use only

Bldg. E4733
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330152
Status: Unutilized
Comment: 2252 sq. ft., needs rehab, most recent use—flammable storage, off-site use only

Bldg. E4734
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330153
Status: Unutilized
Comment: 1114 sq. ft., needs rehab, most recent use—private club, off-site use only

4 Bldgs.
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Location: E5005, E5049, E5050, E5051
Landholding Agency: Army
Property Number: 21200330154
Status: Unutilized
Comment: sq. ft. varies, needs rehab, most recent use—storage, off-site use only

Bldg. E5068
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330155
Status: Unutilized
Comment: 1200 sq. ft., needs rehab, most recent use—fire station, off-site use only

Bldg. 05447
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330160
Status: Unutilized
Comment: 2464 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldgs. 05448, 05449

Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330161
Status: Unutilized
Comment: 6431 sq. ft., needs rehab, most recent use—enlisted UHP, off-site use only

Bldg. 05450
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330162
Status: Unutilized
Comment: 2730 sq. ft., needs rehab, most recent use—admin., off-site use only

Bldgs. 05451, 05455
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330163
Status: Unutilized
Comment: 2730/6431 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. 05453
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330164
Status: Unutilized
Comment: 6431 sq. ft., needs rehab, most recent use—admin., off-site use only

Bldgs. 05456, 05459, 05460
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330165
Status: Unutilized
Comment: 6431 sq. ft., needs rehab, most recent use—enlisted bldg., off-site use only

Bldg. E5609
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330167
Status: Unutilized
Comment: 2053 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. E5611
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330168
Status: Unutilized
Comment: 11,242 sq. ft., needs rehab, most recent use—hazard bldg., off-site use only

Bldg. E5634
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005
Landholding Agency: Army
Property Number: 21200330169
Status: Unutilized
Comment: 200 sq. ft., needs rehab, most recent use—flammable storage, off-site use only

Bldg. E5654
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330171
Status: Unutilized
Comment: 21,532 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. E5854
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330174
Status: Unutilized
Comment: 5166 sq. ft., needs rehab, most recent use—eng/MTN bldg., off-site use only

Bldg. E5942
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330176
Status: Unutilized
Comment: 2147 sq. ft., needs rehab, most recent use—igloo storage, off-site use only

Bldgs. E5952, E5953
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330177
Status: Unutilized
Comment: 100/24 sq. ft., needs rehab, most recent use—compressed air bldg., off-site use only

Bldgs. E7401, E7402
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330178
Status: Unutilized
Comment: 256/440 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. E7407, E7408
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330179
Status: Unutilized
Comment: 1078/762 sq. ft., needs rehab, most recent use—decon facility, off-site use only

Bldg. E7931
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200330182
Status: Unutilized
Comment: needs rehab, most recent use—sewer treatment, off-site use only

Bldg. 1145D
Aberdeen Proving Ground
Harford MD 21005–
Landholding Agency: Army
Property Number: 21200420054
Status: Unutilized
Comment: 898 sq. ft., most recent use—storage, off-site use only

Bldg. 3070A
Aberdeen Proving Ground
Harford MD 21005–
Landholding Agency: Army
Property Number: 21200420055
Status: Unutilized
Comment: 2299 sq. ft., most recent use—heat plant, off-site use only

Bldg. E5026
Aberdeen Proving Ground
Harford MD 21005–
Landholding Agency: Army
Property Number: 21200420056
Status: Unutilized
Comment: 20,536 sq. ft., most recent use—storage, off-site use only

Bldg. 05261
Aberdeen Proving Ground
Harford MD 21005–
Landholding Agency: Army
Property Number: 21200420057
Status: Unutilized
Comment: 10067 sq. ft., most recent use—maintenance, off-site use only

Bldgs. 00733, 00734
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200430063
Status: Unutilized
Comment: 136 sq. ft. each, most recent use—ammo storage, off-site use only

Bldg. 0401A
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200440068
Status: Unutilized
Comment: 220 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. 0748A
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200440069
Status: Unutilized
Comment: 112 sq. ft., needs rehab, most recent use—shelter, off-site use only

Bldg. 01198
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200440070
Status: Unutilized
Comment: 168 sq. ft., needs rehab, most recent use—ordnance, off-site use only

Bldg. 03557
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200440071
Status: Unutilized
Comment: 340 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. E3732
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200440072
Status: Unutilized
Comment: 1080 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. E5876
Aberdeen Proving Grounds
Aberdeen Co: Harford MD 21005–
Landholding Agency: Army
Property Number: 21200440073
Status: Unutilized
Comment: 1192 sq. ft., needs rehab, most recent use—storage, off-site use only

Missouri

Bldg. T1497
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Landholding Agency: Army
Property Number: 21199420441
Status: Underutilized
Comment: 4720 sq. ft., 2-story, presence of lead base paint, most recent use—admin/gen. purpose, off-site use only

Bldg. T2139

Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Landholding Agency: Army
Property Number: 21199420446
Status: Underutilized
Comment: 3663 sq. ft., 1-story, presence of lead base paint, most recent use—admin/gen. purpose, off-site use only

Bldg. T2385
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–
Landholding Agency: Army
Property Number: 21199510115
Status: Excess
Comment: 3158 sq. ft., 1-story, wood frame, most recent use—admin., to be vacated 8/95, off-site use only

Bldg. 2167
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Landholding Agency: Army
Property Number: 21199820179
Status: Unutilized
Comment: 1296 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldgs. 2192, 2196, 2198
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Landholding Agency: Army
Property Number: 21199820183
Status: Unutilized
Comment: 4720 sq. ft., presence of asbestos/lead paint, most recent use—barracks, off-site use only

12 Bldgs Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Location: 07036, 07050, 07054, 07102, 07400, 07401, 08245, 08249, 08251, 08255, 08257, 08261.
Landholding Agency: Army
Property Number: 21200410110
Status: Unutilized
Comment: 7152 sq. ft. 6 plex housing quarters, potential contaminants, off-site use only.

6 Bldg Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Location: 07044, 07106, 07107, 08260, 08281, 08300
Landholding Agency: Army
Property Number: 21200410111
Status: Unutilized
Comment: 9520 sq ft., 8 plex housing quarters, potential contaminants, off-site use only

15 Bldgs
Fort Leaonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Location: 08242, 08243, 08246–08248, 08250, 08252–08254, 08256, 08258–08259, 08262–08263, 08265
Landholding Agency: Army
Property Number: 21200410112
Status: Unutilized
Comment: 4784 sq ft., 4 plex housing quarters, potential contaminants, off-site use only

Bldgs 08283, 08285
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200410113
Status: Unutilized
Comment: 2240 sq ft, 2 plex housing quarters, potential contaminants, off-site use only

15 Bldgs
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–0827
Location: 08267, 08269, 08271, 08273, 08275, 08277, 08279, 08290–08296, 08301
Landholding Agency: Army
Property Number: 21200410114
Status: Unutilized
Comment: 4784 sq ft., 4 plex housing quarters, potential contaminants, off-site use only

Bldg 09432
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200410115
Status: Unutilized
Comment: 8724 sq ft., 6-plex housing quarters, potential contaminants, off-site use only.

Bldgs. 5006 and 5013
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200430064
Status: Unutilized
Comment: 192 & 144 sq. ft., needs repair, most recent use—generator bldg., off-site use only

Bldgs. 13210, 13710
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200430065
Status: Unutilized
Comment: 144 sq. ft. each, needs repair, most recent use—communication, off-site use only

Montana

Bldg. 00405
Fort Harrison
Ft. Harrison Co: Lewis/Clark MT 59636–
Landholding Agency: Army
Property Number: 21200130099
Status: Unutilized
Comment: 3467 sq. ft., most recent use—storage, security limitations

Bldg. T0066
Fort Harrison
Ft. Harrison Co: Lewis/Clark MT 59636–
Landholding Agency: Army
Property Number: 21200130100
Status: Unutilized
Comment: 528 sq. ft., needs rehab, presence of asbestos, security limitations

New Jersey

Bldg. 178
Armament R&D Engineering Center
Picatinny Arsenal Co: Morris NJ 07806–5000
Landholding Agency: Army
Property Number: 21199740312
Status: Unutilized
Comment: 2067 sq. ft., most recent use—research, off-site use only

Bldg. 732
Armament R&D Engineering Center
Picatinny Arsenal Co: Morris NJ 07806–5000
Landholding Agency: Army
Property Number: 21199740315
Status: Unutilized
Comment: 9077 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. 816C
Armament R, D, & Eng. Center
Picatinny Arsenal Co: Morris NJ 07806–5000
Landholding Agency: Army
Property Number: 21200130103
Status: Unutilized
Comment: 144 sq. ft., most recent use—storage, off-site use only

New Mexico

Bldg. 34198
White Sands Missile Range
Dona Ana NM 88002–
Landholding Agency: Army
Property Number: 21200230062
Status: Excess
Comment: 107 sq. ft., most recent use—security, off-site use only

New York

5 Bldgs.
Orangeburg USARC
#206, 207, 208, 218, 223
Orangeburg Co: Rockland NY 10962–2209
Landholding Agency: Army
Property Number: 21200310061
Status: Unutilized
Comment: various sq. ft., need major repairs, presence of lead paint, most recent use—admin/storage, off-site use only

Bldg.1227
U.S. Military Academy
Highlands Co: Orange NY 10996–1592
Landholding Agency: Army
Property Number: 21200440074
Status: Unutilized
Comment: 3800 sq. ft., needs repair, possible asbestos/lead paint, most recent use—maintenance, off-site use only

North Carolina

Bldg. C5536
Fort Bragg
Ft. Bragg Co: Cumberland NC 28310–5000
Landholding Agency: Army
Property Number: 21200130150
Status: Unutilized
Comment: 600 sq. ft., single wide trailer w/metal storage shed, needs major repair, presence of asbestos/lead paint, off-site use only

Oklahoma

Bldg. T–838, Fort Sill
838 Macomb Road
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199220609
Status: Unutilized
Comment: 151 sq. ft., wood frame, 1 story, off-site removal only, most recent use—vet facility (quarantine stable).

Bldg. T–954, Fort Sill
954 Quinette Road
Lawton Co: Comanche OK 73503–5100

Landholding Agency: Army
Property Number: 21199240659
Status: Unutilized
Comment: 3571 sq. ft., 1 story wood frame, needs rehab, off-site use only, most recent use—motor repair shop.

Bldg. T–3325, Fort Sill
3325 Naylor Road
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199240681
Status: Unutilized
Comment: 8832 sq. ft., 1 story wood frame, needs rehab, off-site use only, most recent use—warehouse.

Bldg. T–4226
Fort Sill
Lawton Co: Comanche OK 73503–
Landholding Agency: Army
Property Number: 21199440384
Status: Unutilized
Comment: 114 sq. ft., 1-story wood frame, possible asbestos and lead paint, most recent use—storage, off-site use only

Bldg. P–1015, Fort Sill
Lawton Co: Comanche OK 73501–5100
Landholding Agency: Army
Property Number: 21199520197
Status: Unutilized
Comment: 15402 sq. ft., 1-story, most recent use—storage, off-site use only

Bldg. P–366, Fort Sill
Lawton Co: Comanche OK 73503–
Landholding Agency: Army
Property Number: 21199610740
Status: Unutilized
Comment: 482 sq. ft., possible asbestos, most recent use—storage, off-site use only

Building T–2952
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199710047
Status: Unutilized
Comment: 4,327 sq. ft., possible asbestos and leadpaint, most recent use—motor repair shop, off-site use only

Building P–5042
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199710066
Status: Unutilized
Comment: 119 sq. ft., possible asbestos and leadpaint, most recent use—heatplant, off-site use only

4 Buildings
Fort Sill
Lawton Co: Comanche OK 73503–5100
Location: T–6465, T–6466, T–6467, T–6468
Landholding Agency: Army
Property Number: 21199710086
Status: Unutilized
Comment: various sq. ft., possible asbestos and leadpaint, most recent use—range support, off site use only

Bldg. T–810
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730350
Status: Unutilized
Comment: 7205 sq. ft., possible asbestos/lead paint, most recent use—hay storage, off-site use only

Bldgs. T–837, T–839
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730351
Status: Unutilized
Comment: approx. 100 sq. ft. each, possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. P–934
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730353
Status: Unutilized
Comment: 402 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. T–1468, T–1469
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730357
Status: Unutilized
Comment: 114 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–1470
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730358
Status: Unutilized
Comment: 3120 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. T–1954, T–2022
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730362
Status: Unutilized
Comment: approx. 100 sq. ft. each, possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–2184
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730364
Status: Unutilized
Comment: 454 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. T–2186, T–2188, T–2189
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730366
Status: Unutilized
Comment: 1656—3583 sq. ft., possible asbestos/lead paint, most recent use—vehicle maint. shop, off-site use only

Bldg. T–2187
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730367
Status: Unutilized
Comment: 1673 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. T–2291 thru T–2296
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730372
Status: Unutilized
Comment: 400 sq. ft. each, possible asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. T–3001, T–3006
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730383
Status: Unutilized
Comment: approx. 9300 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–3314
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730385
Status: Unutilized
Comment: 229 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. T–5041
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730409
Status: Unutilized
Comment: 763 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–5420
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730414
Status: Unutilized
Comment: 189 sq. ft., possible asbestos/lead paint, most recent use—fuel storage, off-site use only

Bldg. T–7775
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199730419
Status: Unutilized
Comment: 1452 sq. ft., possible asbestos/lead paint, most recent use—private club, off-site use only

4 Bldgs.
Fort Sill
P–617, P–1114, P–1386, P–1608
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910133
Status: Unutilized
Comment: 106 sq. ft., possible asbestos/lead paint, most recent use—utility plant, off-site use only

Bldg. P–746
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910135
Status: Unutilized
Comment: 6299 sq. ft., possible asbestos/lead paint, most recent use—admin., off-site use only

Bldgs. P–2581, P–2773
Fort Sill
Lawton Co: Comanche OK 73503–5100

Landholding Agency: Army
Property Number: 21199910140
Status: Unutilized
Comment: 4093 and 4129 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. P–2582
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910141
Status: Unutilized
Comment: 3672 sq. ft., possible asbestos/lead paint, most recent use—admin., off-site use only

Bldgs. P–2912, P–2921, P–2944
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910144
Status: Unutilized
Comment: 1390 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. P–2914
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910146
Status: Unutilized
Comment: 1236 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. P–5101
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910153
Status: Unutilized
Comment: 82 sq. ft., possible asbestos/lead paint, most recent use—gas station, off-site use only

Bldg. S–6430
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910156
Status: Unutilized
Comment: 2080 sq. ft., possible asbestos/lead paint, most recent use—range support, off-site use only

Bldg. T–6461
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910157
Status: Unutilized
Comment: 200 sq. ft., possible asbestos/lead paint, most recent use—range support, off-site use only

Bldg. T–6462
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910158
Status: Unutilized
Comment: 64 sq. ft., possible asbestos/lead paint, most recent use—control tower, off-site use only

Bldg. P–7230
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21199910159
Status: Unutilized
Comment: 160 sq. ft., possible asbestos/lead paint, most recent use—transmitter bldg., off-site use only

Bldg. S–4023
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200010128
Status: Unutilized
Comment: 1200 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. P–747
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120120
Status: Unutilized
Comment: 9232 sq. ft., possible asbestos/lead paint, most recent use—lab, off-site use only

Bldg. P–842
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120123
Status: Unutilized
Comment: 192 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–911
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120124
Status: Unutilized
Comment: 3080 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. P–1672
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120126
Status: Unutilized
Comment: 1056 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. S–2362
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120127
Status: Unutilized
Comment: 64 sq. ft., possible asbestos/lead paint, most recent use—gatehouse, off-site use only

Bldg. P–2589
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120129
Status: Unutilized
Comment: 3672 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Pennsylvania

5 Bldgs.
Carlisle Barracks
00441 thru 00445
Carlisle Co: Cumberland PA 17013–
Landholding Agency: Army
Property Number: 21200430066
Status: Unutilized
Comment: 4238 sq. ft. each, presence of asbestos, most recent use—residential, off-site use only

South Carolina

Bldg. 3499
Fort Jackson
Ft. Jackson Co: Richland SC 29207–
Landholding Agency: Army
Property Number: 21199730310
Status: Unutilized
Comment: 3724 sq. ft., needs repair, most recent use—admin.

Bldg. 2441
Fort Jackson
Ft. Jackson Co: Richland SC 29207–
Landholding Agency: Army
Property Number: 21199820187
Status: Unutilized
Comment: 2160 sq. ft., needs repair, most recent use—admin.

Bldg. 3605
Fort Jackson
Ft. Jackson Co: Richland SC 29207–
Landholding Agency: Army
Property Number: 21199820188
Status: Unutilized
Comment: 711 sq. ft., needs repair, most recent use—storage

Bldg. 1765
Fort Jackson
Ft. Jackson Co: Richland SC 29207–
Landholding Agency: Army
Property Number: 21200030109
Status: Unutilized
Comment: 1700 sq. ft., need repairs, presence of asbestos/lead paint, most recent use—training bldg., off-site use only

Texas

Bldg. 7137
Fort Bliss
El Paso Co: El Paso TX 79916-
Landholding Agency: Army
Property Number: 21199640564
Status: Unutilized
Comment: 35,736 sq. ft., 3-story, most recent use—housing, off-site use only

Bldg. 92043
Fort Hood
Ft. Hood Co: Bell TX 76544-
Landholding Agency: Army
Property Number: 21200020206
Status: Unutilized
Comment: 450 sq. ft., most recent use—storage, off-site use only

Bldg. 92044
Fort Hood
Ft. Hood Co: Bell TX 76544-
Landholding Agency: Army
Property Number: 21200020207
Status: Unutilized
Comment: 1920 sq. ft., most recent use—admin., off-site use only

Bldg. 92045
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200020208
Status: Unutilized
Comment: 2108 sq. ft., most recent use—maint., off-site use only

Bldg. 120
Fort Hood

Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220137
Status: Unutilized
Comment: 1450 sq. ft., most recent use—dental clinic, off-site use only

Bldg. 56305
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220143
Status: Unutilized
Comment: 2160 sq. ft., most recent use—admin., off-site use only

Bldg. 56402
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220144
Status: Unutilized
Comment: 2680 sq. ft., most recent use—recreation center, off-site use only

Bldgs. 56403, 56405
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220145
Status: Unutilized
Comment: 480 sq. ft., most recent use—shower, off-site use only

Bldgs. 56620, 56621
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220146
Status: Unutilized
Comment: 1120 sq. ft., most recent use—shower, off-site use only

Bldgs. 56626, 56627
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220147
Status: Unutilized
Comment: 1120 sq. ft., most recent use—shower, off-site use only

Bldg. 56628
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220148
Status: Unutilized
Comment: 1133 sq. ft., most recent use—shower, off-site use only

Bldgs. 56630, 56631
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220149
Status: Unutilized
Comment: 1120 sq. ft., most recent use—shower, off-site use only

Bldgs. 56636, 56637
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220150
Status: Unutilized
Comment: 1120 sq. ft., most recent use—shower, off-site use only

Bldg. 56638
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220151
Status: Unutilized
Comment: 1133 sq. ft., most recent use—shower, off-site use only

Bldgs. 56703, 56708
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220152
Status: Unutilized
Comment: 1306 sq. ft., most recent use—shower, off-site use only

Bldg. 56758
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220154
Status: Unutilized
Comment: 1133 sq. ft., most recent use—shower, off-site use only

Bldgs. P6220, P6222
Fort Sam Houston
Camp Bullis
San Antonio Co: Bexar TX
Landholding Agency: Army
Property Number: 21200330197
Status: Unutilized
Comment: 384 sq. ft., most recent use—carport/storage, off-site use only

Bldgs. P6224, P6226
Fort Sam Houston
Camp Bullis
San Antonio Co: Bexar TX
Landholding Agency: Army
Property Number: 21200330198
Status: Unutilized
Comment: 384 sq. ft., most recent use—carport/storage, off-site use only

Bldg. 04200
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200420065
Status: Unutilized
Comment: 2100 sq. ft., presence of asbestos, most recent use—admin., off-site use only

29 Bldgs.
Fort Sam Houston
Canyon Lake Co: TX
Location: S–34 thru S–39, S–40 thru S–63
Landholding Agency: Army
Property Number: 21200440076
Status: Unutilized
Comment: 924 sq. ft., mobile homes, off-site use only

Virginia

Bldgs. 1516, 1517, 1552, 1567
Fort Eustis
Ft. Eustis VA 23604–
Landholding Agency: Army
Property Number: 21200130154
Status: Unutilized
Comment: 2892 & 4720 sq. ft., most recent use—dining/barracks/admin, off-site use only

Bldg. 1559
Fort Eustis
Ft. Eustis VA 23604–
Landholding Agency: Army
Property Number: 21200130156
Status: Unutilized
Comment: 2892 sq. ft., most recent use—storage, off-site use only

Bldg. T–707
Fort Eustis
Ft. Eustis VA 23604–
Landholding Agency: Army
Property Number: 21200330199
Status: Unutilized
Comment: 3763 sq. ft., most recent use—chapel, off-site use only

Bldg. 01025
Fort Belvoir
Ft. Belvoir Co: Fairfax VA 22060–
Landholding Agency: Army
Property Number: 21200440108
Status: Unutilized
Comment: 3594 sq. ft., presence of asbestos, most recent use—chapel, off-site use only

Bldgs. 01804, 01824
Fort Belvoir
Ft. Belvoir Co: Fairfax VA 22060–
Landholding Agency: Army
Property Number: 21200440109
Status: Unutilized
Comment: 3960 sq. ft., presence of asbestos, most recent use—chapel, off-site use only

Washington

Bldg. CO909, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–9500
Landholding Agency: Army
Property Number: 21199630205
Status: Unutilized
Comment: 1984 sq. ft., possible asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 1164, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–9500
Landholding Agency: Army
Property Number: 21199630213
Status: Unutilized
Comment: 230 sq. ft., possible asbestos/lead paint, most recent use—storehouse, off-site use only

Bldg. 1307, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–9500
Landholding Agency: Army
Property Number: 21199630216
Status: Unutilized
Comment: 1092 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 1309, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–9500
Landholding Agency: Army
Property Number: 21199630217
Status: Unutilized
Comment: 1092 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 2167, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–9500
Landholding Agency: Army
Property Number: 21199630218
Status: Unutilized
Comment: 288 sq. ft., possible asbestos/lead paint, most recent use—warehouse, off-site use only

Bldg. 4078, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–9500
Landholding Agency: Army
Property Number: 21199630219
Status: Unutilized
Comment: 10200 sq. ft., needs rehab, possible asbestos/lead paint, most recent use—warehouse, off-site use only

Bldg. 9599, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–9500

Landholding Agency: Army
Property Number: 21199630220
Status: Unutilized
Comment: 12366 sq. ft., possible asbestos/lead paint, most recent use—warehouse, off-site use only

Bldg. A1404, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199640570
Status: Unutilized
Comment: 557 sq. ft., needs rehab, most recent use—storage, off-site use only

Bldg. EO347
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199710156
Status: Unutilized
Comment: 1800 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. B1008, Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199720216
Status: Unutilized
Comment: 7387 sq. ft., 2-story, needs rehab, possible asbestos/lead paint, most recent use—medical clinic, off-site use only

Bldgs. CO509, CO709, CO720
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199810372
Status: Unutilized
Comment: 1984 sq. ft., possible asbestos/lead paint, needs rehab, most recent use—storage, off-site use only

Bldg. 5162
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199830419
Status: Unutilized
Comment: 2360 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—office, off-site use only

Bldg. 5224
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199830433
Status: Unutilized
Comment: 2360 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—educ. fac., off-site use only

Bldg. U001B
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920237
Status: Excess
Comment: 54 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—control tower, off-site use only

Bldg. U001C
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920238
Status: Unutilized
Comment: 960 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—supply, off-site use only

10 Bldgs.
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: U002B, U002C, U005C, U015I, U016E, U019C, U022A, U028B, 0091A, U093C
Landholding Agency: Army
Property Number: 21199920239
Status: Excess
Comment: 600 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—range house, off-site use only

6 Bldgs.
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: U003A, U004B, U006C, U015B, U016B, U019B
Landholding Agency: Army
Property Number: 21199920240
Status: Unutilized
Comment: 54 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—control tower, off-site use only

Bldg. U004D
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920241
Status: Unutilized
Comment: 960 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—supply, off-site use only

Bldg. U005A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920242
Status: Unutilized
Comment: 360 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—control tower, off-site use only

7 Bldgs.
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: U014A, U022B, U023A, U043B, U059B, U060A, U101A
Landholding Agency: Army
Property Number: 21199920245
Status: Excess
Comment: needs repair, presence of asbestos/lead paint, most recent use—ofc/tower/support, off-site use only

Bldg. U015J
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920246
Status: Excess
Comment: 144 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—tower, off-site use only

Bldg. U018B
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920247
Status: Unutilized
Comment: 121 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—range house, off-site use only

Bldg. U018C
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920248
Status: Unutilized
Comment: 48 sq. ft., needs repair, presence of asbestos/lead paint, off-site use only

Bldg. U024D
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920250
Status: Unutilized
Comment: 120 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—ammo bldg., off-site use only

Bldg. U027A
Fort Lewis
Ft. Lewis Co: Pierce WA
Landholding Agency: Army
Property Number: 21199920251
Status: Excess
Comment: 64 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—tire house, off-site use only

Bldg. U031A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920253
Status: Excess
Comment: 3456 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—line shed, off-site use only

Bldg. U031C
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920254
Status: Unutilized
Comment: 32 sq. ft., needs repair, presence of asbestos/lead paint, off-site use only

Bldg. U040D
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920255
Status: Excess
Comment: 800 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—range house, off-site use only

Bldgs. U052C, U052H
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920256
Status: Excess
Comment: various sq. ft., needs repair, presence of asbestos/lead paint, most recent use—range house, off-site use only

Bldgs. U035A, U035B
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920257
Status: Excess
Comment: 192 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—shelter, off-site use only

Bldg. U035C
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920258
Status: Excess
Comment: 242 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—range house, off-site use only

Bldg. U039A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920259
Status: Excess
Comment: 36 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—control tower, off-site use only

Bldg. U039B
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920260
Status: Excess
Comment: 1600 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—grandstand/bleachers, off-site use only

Bldg. U039C
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920261
Status: Excess
Comment: 600 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—support, off-site use only

Bldg. U043A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920262
Status: Excess
Comment: 132 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—range house, off-site use only

Bldg. U052A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920263
Status: Excess
Comment: 69 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—tower, off-site use only

Bldg. U052E
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920264
Status: Excess
Comment: 600 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. U052G
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920265
Status: Excess
Comment: 1600 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—shelter, off-site use only

3 Bldgs.
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: U058A, U103A, U018A
Landholding Agency: Army
Property Number: 21199920266
Status: Excess
Comment: 36 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—control tower, off-site use only

Bldg. U059A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920267
Status: Excess
Comment: 16 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—tower, off-site use only

Bldg. U093B
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920268
Status: Excess
Comment: 680 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—range house, off-site use only

4 Bldgs.
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: U101B, U101C, U507B, U557A
Landholding Agency: Army
Property Number: 21199920269
Status: Excess
Comment: 400 sq. ft., needs repair, presence of asbestos/lead paint, off-site use only

Bldg. U110B
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920272
Status: Excess
Comment: 138 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—support, off-site use only

6 Bldgs.
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Location: U111A, U015A, U024E, U052F, U109A, U110A
Landholding Agency: Army
Property Number: 21199920273
Status: Excess
Comment: 1000 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—support/shelter/mess, off-site use only

Bldg. U112A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920274
Status: Excess
Comment: 1600 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—shelter, off-site use only

Bldg. U115A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920275
Status: Excess
Comment: 36 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—tower, off-site use only

Bldg. U507A
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920276
Status: Excess
Comment: 400 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—support, off-site use only

Bldg. C0120
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920281
Status: Excess
Comment: 384 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—scale house, off-site use only

Bldg. 01205
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920290
Status: Excess
Comment: 87 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—storehouse, off-site use only

Bldg. 01259
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920291
Status: Excess
Comment: 16 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 01266
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920292
Status: Excess
Comment: 45 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—shelter, off-site use only

Bldg. 1445
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920294
Status: Excess
Comment: 144 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—generator bldg., off-site use only

Bldgs. 03091, 03099
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920296
Status: Excess
Comment: various sq. ft., needs repair, presence of asbestos/lead paint, most recent use—sentry station, off-site use only

Bldg. 4040
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920298
Status: Excess
Comment: 8326 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—shed, off-site use only

Bldgs. 4072, 5104
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920299
Status: Excess
Comment: 24/36 sq. ft., needs repair, presence of asbestos/lead paint, off-site use only

Bldg. 4295
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–

Landholding Agency: Army
Property Number: 21199920300
Status: Excess
Comment: 48 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 6191
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920303
Status: Excess
Comment: 3663 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—exchange branch, off-site use only

Bldgs. 08076, 08080
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920304
Status: Excess
Comment: 3660/412 sq. ft., needs repair, presence of asbestos/lead paint, off-site use only

Bldg. 08093
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920305
Status: Excess
Comment: 289 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—boat storage, off-site use only

Bldg. 8279
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920306
Status: Excess
Comment: 210 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—fuel disp. fac., off-site use only

Bldgs. 8280, 8291
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920307
Status: Excess
Comment: 800/464 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 8956
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920308
Status: Excess
Comment: 100 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 9530
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920309
Status: Excess
Comment: 64 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—sentry station, off-site use only

Bldg. 9574
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920310
Status: Excess
Comment: 6005 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—veh. shop., off-site use only

Bldg. 9596
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 21199920311
Status: Excess
Comment: 36 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—gas station, off-site use only

Land (by State)

Georgia

Land (Railbed)
Fort Benning
Ft. Benning Co: Muscogee GA 31905–
Landholding Agency: Army
Property Number: 21199440440
Status: Unutilized
Comment: 17.3 acres extending 1.24 miles, no known utilities potential

Ohio

Land
Defense Supply Center
Columbus Co: Franklin OH 43216–5000
Landholding Agency: Army
Property Number: 21200340094
Status: Excess
Comment: 11 acres, railroad access

South Carolina

One Acre
Fort Jackson
Columbia Co: Richland SC 29207–
Landholding Agency: Army
Property Number: 21200110089
Status: Underutilized
Comment: approx. 1 acre

Texas

1 acre
Fort Sam Houston
San Antonio Co: Bexar TX 78234–
Landholding Agency: Army
Property Number: 21200440075
Status: Excess
Comment: 1 acre, grassy area

Suitable/Unavailable Properties

Buildings (by State)

Alabama

Bldg. 01433
Fort Rucker
Ft. Rucker Co: Dale AL 36362–
Landholding Agency: Army
Property Number: 21200220098
Status: Excess
Comment: 800 sq. ft., most recent use—office, off-site use only

Colorado

Bldg. T–203
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200340079
Status: Unutilized
Comment: 1628 sq. ft., presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. T–223 thru T–227
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200340081
Status: Unutilized
Comment: 9000 sq. ft., presence of asbestos/lead paint, most recent use—warehouse, off-site use only

Bldg. S6222
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200340082
Status: Unutilized
Comment: 19,225 sq. ft., presence of asbestos/lead paint, most recent use—office, off-site use only

Bldg. S6264
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200340084
Status: Unutilized
Comment: 19,499 sq. ft., most recent use—office, off-site use only

Bldg. 1040
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200410088
Status: Unutilized
Comment: 13,280 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—dining facility, off-site use only

Bldgs. P1042, P1043, P1044
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200410089
Status: Unutilized
Comment: 40,639 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—barracks, off-site use only

Bldg. 1045
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200410090
Status: Unutilized
Comment: 12,115 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—admin/supply, off-site use only

Bldgs. P1046, P1047
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200410091
Status: Unutilized
Comment: 40,639 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—barracks, off-site use only

Bldg. P1049
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200410092
Status: Unutilized
Comment: 12,115 sq. ft., needs repair, presence of asbestos/lead paint, most recent use—admin/supply, off-site use only

Bldg. S6220
Fort Carson

Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200420175
Status: Unutilized
Comment: 12,361 sq. ft., presence of asbestos, most recent use—admin., off-site use only

Bldg. S6285
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200420176
Status: Unutilized
Comment: 19,478 sq. ft., most recent use—admin., off-site use only

Bldg. S6287
Fort Carson
Ft. Carson Co: El Paso CO 80913–
Landholding Agency: Army
Property Number: 21200420177
Status: Unutilized
Comment: 10,076 sq. ft., presence of asbestos, most recent use—admin., off-site use only

Georgia

Bldg. 2410
Fort Gordon
Ft. Gordon Co: Richmond GA 30905–
Landholding Agency: Army
Property Number: 21200140076
Status: Unutilized
Comment: 8480 sq. ft., needs rehab, potential asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–920
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200240083
Status: Excess
Comment: 13,337 sq. ft., most recent use—office, off-site use only

Bldgs. 00960, 00961, 00963
Fort Benning
Ft. Benning Co: Chattahoochee GA
Landholding Agency: Army
Property Number: 21200330107
Status: Unutilized
Comment: 11,110 sq. ft., most recent use—housing, off-site use only

Bldg. T201
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420002
Status: Excess
Comment: 1828 sq. ft., most recent use—credit union, off-site use only

Bldg. T202
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420003
Status: Excess
Comment: 5602 sq. ft., most recent use—headquarters bldg., off-site use only

Bldg. T222
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420004
Status: Excess
Comment: 2891 sq. ft., most recent use—headquarters bldg., off-site use only

Bldg. P223
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420005
Status: Excess
Comment: 6434 sq. ft., most recent use—headquarters bldg., off-site use only

Bldg. P224
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420006
Status: Excess
Comment: 6434 sq. ft., most recent use—enlisted bldg., off-site use only

Bldg. T234
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420008
Status: Excess
Comment: 2624 sq. ft., most recent use—admin., off-site use only

Bldg. T235
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420009
Status: Excess
Comment: 1842 sq. ft., most recent use—headquarters bldg., off-site use only

Bldg. T702
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420010
Status: Excess
Comment: 9190 sq. ft., most recent use—storage, off-site use only

Bldg. T703
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420011
Status: Excess
Comment: 9190 sq. ft., most recent use—storage, off-site use only

Bldg. T704
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420012
Status: Excess
Comment: 9190 sq. ft., most recent use—storage, off-site use only

Bldg. P813
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420013
Status: Excess
Comment: 43,055 sq. ft., most recent use—maint. hanger/Co Hq., off-site use only

Bldgs. S843, S844, S845
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420014
Status: Excess
Comment: 9383 sq. ft., most recent use—maint hanger, off-site use only

Bldg. P925
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420015
Status: Excess
Comment: 27,681 sq. ft., most recent use—fitness center, off-site use only

Bldg. S1227
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420016
Status: Excess
Comment: 2750 sq. ft., most recent use—admin., off-site use only

Bldg. S1248
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420017
Status: Excess
Comment: 1450 sq. ft., most recent use—police station, off-site use only

Bldg. S1251
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420018
Status: Excess
Comment: 3300 sq. ft., most recent use—police station, off-site use only

Bldg. T1254
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420019
Status: Excess
Comment: 4720 sq. ft., most recent use—transient UPH, off-site use only

Bldg. S1259
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420020
Status: Excess
Comment: 1750 sq. ft., most recent use—admin., off-site use only

Bldg. S1260
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420021
Status: Excess
Comment: 1750 sq.ft., most recent use—exchange service outlet, off-site use only

Bldg. P1275
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420022
Status: Excess
Comment: 138,032 sq. ft., most recent use—dining facility, off-site use only

Bldg. P1276
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420023
Status: Excess
Comment: 138,032 sq. ft., most recent use—headquarters bldg., off-site use only

Bldg. P1277
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420024
Status: Excess

Comment: 13,981 sq. ft., most recent use—barracks/dining, off-site use only
Bldg. T1412
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420025
Status: Excess
Comment: 9186 sq. ft., most recent use—warehouse, off-site use only
Bldg. T1413
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420026
Status: Excess
Comment: 21,483 sq. ft., most recent use—fitness center/warehouse, off-site use only
Bldg. P8058
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420028
Status: Excess
Comment: 1808 sq. ft., most recent use—control tower, off-site use only
Bldg. 8658
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420029
Status: Excess
Comment: 8470 sq. ft., most recent use—storage, off-site use only
Bldg. 8659
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420030
Status: Excess
Comment: 8470 sq. ft., most recent use—storage, off-site use only
Bldgs. 8675, 8676
Hunter Army Airfield
Garrison Co: Chatham GA 31409–
Landholding Agency: Army
Property Number: 21200420031
Status: Excess
Comment: 4000 sq. ft., most recent use—ship/recv facility, off-site use only
Bldg. 5962–5966
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420035
Status: Excess
Comment: 2421 sq. ft., most recent use—igloo storage, off-site use only
Bldgs. 5967–5971
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420036
Status: Excess
Comment: 1813 sq. ft., most recent use—igloo storage, off-site use only
Bldgs. 5974–5977
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420037
Status: Excess
Comment: 400 sq. ft., most recent use—igloo storage, off-site use only
Bldg. 5978
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420038
Status: Excess
Comment: 1344 sq. ft., most recent use—igloo storage, off-site use only
Bldg. 5981
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420039
Status: Excess
Comment: 2028 sq. ft., most recent use—ammo storage, off-site use only
Bldgs. 5984–5988
Fort Benning
Ft. Benning Co: Chatachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420040
Status: Excess
Comment: 1816 sq. ft., most recent use—igloo storage, off-site use only
Bldg. 5993
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420041
Status: Excess
Comment: 960 sq. ft., most recent use—storage, off-site use only
Bldg. 5994
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420042
Status: Excess
Comment: 2016 sq. ft., most recent use—ammo storage, off-site use only
Bldg. 5995
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420043
Status: Excess
Comment: 114 sq. ft., most recent use—storage, off-site use only
Bldg. 9000
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420045
Status: Excess
Comment: 9313 sq. ft., most recent use—headquarters bldg., off-site use only
Bldgs. 9002, 9005
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420046
Status: Excess
Comment: 3555 sq. ft., most recent use—classroom, off-site use only
Bldg. 9025
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420047
Status: Excess
Comment: 3707 sq. ft., most recent use—headquarters bldg., off-site use only
Bldg. 9026
Fort Benning
Ft. Benning Co: Chattachoochee GA 31905–
Landholding Agency: Army
Property Number: 21200420048
Status: Excess
Comment: 3867 sq. ft., most recent use—headquarters bldg., off-site use only
Bldg. T01
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420181
Status: Excess
Comment: 11,682 sq. ft., most recent use—admin., off-site use only
Bldg. T04
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420182
Status: Excess
Comment: 8292 sq. ft., most recent use—admin., off-site use only
Bldg. T05
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420183
Status: Excess
Comment: 7992 sq. ft., most recent use—admin., off-site use only
Bldg. T06
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420184
Status: Excess
Comment: 3305 sq. ft., most recent use—communication center, off-site use only
Bldg. T08
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420185
Status: Excess
Comment: 7670 sq. ft., most recent use—admin., off-site use only
Bldg. 00037
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420186
Status: Excess
Comment: 2833 sq. ft., most recent use—admin., off-site use only
Bldg. T55
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420187
Status: Excess
Comment: 6490 sq. ft., most recent use—admin., off-site use only
Bldg. T85
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420188
Status: Excess
Comment: 3283 sq. ft., most recent use—post chapel, off-site use only
Bldg. T131
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army

Property Number: 21200420189
Status: Excess
Comment: 4720 sq. ft., most recent use—admin., off-site use only

Bldg. T132
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420190
Status: Excess
Comment: 4720 sq. ft., most recent use—admin., off-site use only

Bldg. T157
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420191
Status: Excess
Comment: 1440 sq. ft., most recent use—education center, off-site use only

Bldg. 00916
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420192
Status: Excess
Comment: 642 sq. ft., most recent use—warehouse, off-site use only

Bldg. 00923
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420193
Status: Excess
Comment: 2436 sq. ft., most recent use—admin., off-site use only

Bldg. P925
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420195
Status: Excess
Comment: 3115 sq. ft., most recent use—motor repair shop, off-site use only

Bldg. 00926
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420196
Status: Excess
Comment: 357 sq. ft., most recent use—warehouse, off-site use only

Bldg. 01002
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420197
Status: Excess
Comment: 9267 sq. ft., most recent use—maintenance shop, off-site use only

Bldg. 01003
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420198
Status: Excess
Comment: 9267 sq. ft., most recent use—admin, off-site use only

Bldg. T1004
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420199
Status: Excess
Comment: 9272 sq. ft., most recent use—warehouse, off-site use only

Bldg. T1023
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420200
Status: Excess
Comment: 9267 sq. ft., most recent use—warehouse, off-site use only

Bldg. T1041
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420201
Status: Excess
Comment: 1626 sq. ft., most recent use—storage, off-site use only

Bldg. T1043
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420202
Status: Excess
Comment: 3825 sq. ft., most recent use—admin., off-site use only

Bldg. T1045
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420203
Status: Excess
Comment: 600 sq. ft., most recent use—shop, off-site use only

Bldg. T106
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420204
Status: Excess
Comment: 650 sq. ft., most recent use—heat plant bldg., off-site use only

Bldg. T1047
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420205
Status: Excess
Comment: 3000 sq. ft., most recent use—wash. platform/org., off-site use only

Bldg. T1049
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420206
Status: Excess
Comment: 768 sq. ft., most recent use—engine test facility, off-site use only

Bldg. T1050
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420207
Status: Excess
Comment: 3114 sq. ft., most recent use—shop, off-site use only

Bldg. T1051
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420208
Status: Excess
Comment: 12,205 sq. ft., most recent use—shop, off-site use only

Bldg. T1056
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420209
Status: Excess
Comment: 18,260 sq. ft., most recent use—shop, off-site use only

Bldg. T1057
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420210
Status: Excess
Comment: 18,260 sq. ft., most recent use—warehouse, off-site use only

Bldg. T1058
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420211
Status: Excess
Comment: 18,260 sq. ft., most recent use—storage, off-site use only

Bldg. T1062
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420212
Status: Excess
Comment: 5520 sq. ft., most recent use—general purpose, off-site use only

Bldg. T1069
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420213
Status: Excess
Comment: 14,096 sq. ft., most recent use—shop, off-site use only

Bldg. T1083
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420214
Status: Excess
Comment: 2816 sq .ft., most recent use—storage, off-site use only

Bldg. 19101
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420215
Status: Excess
Comment: 6773 sq. ft., most recent use—simulator bldg., off-site use only

Bldg. 19102
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420216
Status: Excess
Comment: 3250 sq. ft., most recent use—simulator bldg., off-site use only

Bldg. T19111
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420217
Status: Excess
Comment: 1440 sq. ft., most recent use—admin., off-site use only

Bldg. 19112
Fort Stewart

Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420218
Status: Excess
Comment: 1344 sq. ft., most recent use—storage, off-site use only

Bldg. 19113
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420219
Status: Excess
Comment: 1440 sq. ft., most recent use—admin., off-site use only

Bldg. T19201
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420220
Status: Excess
Comment: 960 sq. ft., most recent use—physical fitness center, off-site use only

Bldg. 19202
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420221
Status: Excess
Comment: 1210 sq. ft., most recent use—community center, off-site use only

Bldg. 19204 thru 19207
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420222
Status: Excess
Comment: 960 sq. ft., most recent use—admin., off-site use only

Bldgs. 19208 thru 19211
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420223
Status: Excess
Comment: 1540 sq. ft., most recent use—general installation bldg., off-site use only

Bldg. 19212
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420224
Status: Excess
Comment: 1248 sq. ft., off-site use only

Bldg. 19213
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420225
Status: Excess
Comment: 1540 sq. ft., most recent use—general installation bldg., off-site use only

Bldg. 19214
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420226
Status: Excess
Comment: 1796 sq. ft., most recent use—transient UPH, off-site use only

Bldg. 19215
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420227
Status: Excess
Comment: 1948 sq. ft., most recent use—transient UPH, off-site use only

Bldg. 19216
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420228
Status: Excess
Comment: 1540 sq. ft., most recent use—transient UPH, off-site use only

Bldg. 19217
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420229
Status: Excess
Comment: 120 sq. ft., most recent use—nav aids bldg., off-site use only

Bldg. 19218
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420230
Status: Excess
Comment: 2925 sq. ft., most recent use—general installation bldg., off-site use only

Bldgs. 19219, 19220
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420231
Status: Excess
Comment: 1200 sq. ft., most recent use—general installation bldg., off-site use only

Bldg. 19223
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420232
Status: Excess
Comment: 6433 sq. ft., most recent use—transient UPH, off-site use only

Bldg. 19225
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420233
Status: Excess
Comment: 4936 sq. ft., most recent use—dining facility, off-site use only

Bldg. 19226
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420234
Status: Excess
Comment: 136 sq. ft., most recent use—general purpose installation bldg., off-site use only

Bldg. T19228
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420235
Status: Excess
Comment: 400 sq. ft., most recent use—admin., off-site use only

Bldg. 19229
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420236
Status: Excess
Comment: 640 sq. ft., most recent use—vehicle shed, off-site use only

Bldg. 19232
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420237
Status: Excess
Comment: 96 sq. ft., most recent use—general purpose installation, off-site use only

Bldg. 19233
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420238
Status: Excess
Comment: 48 sq. ft., most recent use—fire support, off-site use only

Bldg. 19236
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420239
Status: Excess
Comment: 1617 sq. ft., most recent use—transient UPH, off-site use only

Bldg. 19238
Fort Stewart
Ft. Stewart Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 21200420240
Status: Excess
Comment: 738 sq. ft., off-site use only

Indiana

Bldg. 301
Fort Benjamin Harrison
Indianapolis Co: Marion IN 45216–
Landholding Agency: Army
Property Number: 21200320098
Status: Unutilized
Comment: 1564 sq. ft., possible asbestos/lead paint, most recent use—storage shed, off-site use only

Bldg. 302
Fort Benjamin Harrison
Indianapolis Co: Marion IN 46216–
Landholding Agency: Army
Property Number: 21200320099
Status: Unutilized
Comment: 400 sq. ft., possible asbestos/lead paint, most recent use—switch station, off-site use only

Bldg. 303
Fort Benjamin Harrison
Indianapolis Co: Marion IN 46216–
Landholding Agency: Army
Property Number: 21200320100
Status: Unutilized
Comment: 462 sq. ft., possible asbestos/lead paint, most recent use—heat plant bldg., off-site use only

Bldg. 304
Fort Benjamin Harrison
Indianapolis Co: Marion IN 46216–
Landholding Agency: Army
Property Number: 21200320101
Status: Unutilized
Comment: 896 sq. ft., possible asbestos/lead paint, most recent use—heat plant bldg., off-site use only

Bldg. 334
Fort Benjamin Harrison
Indianapolis Co: Marion IN 46216–
Landholding Agency: Army

Property Number: 21200320102
Status: Unutilized
Comment: 652 sq. ft., possible asbestos/lead paint, off-site use only

Bldg. 337
Fort Benjamin Harrison
Indianapolis Co: Marion IN 46216–
Landholding Agency: Army
Property Number: 21200320103
Status: Unutilized
Comment: 675 sq. ft., possible asbestos/lead paint, off-site use only

Maryland

Bldg. 2282C
Fort George G. Meade
Fort Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 21200230059
Status: Unutilized
Comment: 46 sq. ft., needs rehab, most recent use—sentry tower, off-site use only

Bldg. 8608
Fort George G. Meade
Ft. Meade MD 20755–5115
Landholding Agency: Army
Property Number: 21200410099
Status: Unutilized
Comment: 2372 sq. ft., concrete block, most recent use—PX exchange, off-site use only

Bldg. 8612
Fort George G. Meade
Ft. Meade MD 20755–5115
Landholding Agency: Army
Property Number: 21200410101
Status: Unutilized
Comment: 2372 sq. ft., concrete block, most recent use—family life ctr., off-site use only

Missouri

Bldg. 1230
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200340087
Status: Unutilized
Comment: 9160 sq. ft., most recent use—training, off-site use only

Bldg. 1621
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200340088
Status: Unutilized
Comment: 2400 sq. ft., most recent use—exchange branch, off-site use only

Bldg. 6822
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200340091
Status: Unutilized
Comment: 4000 sq. ft., most recent use—storage, off-site use only

Bldg. 9000
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200340092
Status: Unutilized
Comment: 1440 sq. ft., most recent use—welcome center, off-site use only

Bldg. 10201
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200340093
Status: Unutilized
Comment: 1200 sq. ft., most recent use—storage, off-site use only

Bldg. 5760
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200410102
Status: Unutilized
Comment: 2000 sq. ft., most recent use—classroom, off-site use only

Bldg. 5762
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200410103
Status: Unutilized
Comment: 104 sq. ft., off-site use only

Bldg. 5763
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200410104
Status: Unutilized
Comment: 120 sq. ft., most recent use—observation tower, off-site use only

Bldg. 5765
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200410105
Status: Unutilized
Comment: 800 sq. ft., most recent use—range support, off-site use only

Bldg. 5760
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200420059
Status: Unutilized
Comment: 2000 sq. ft., most recent use—classroom, off-site use only

Bldg. 5762
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200420060
Status: Unutilized
Comment: 104 sq. ft., off-site use only

Bldg. 5763
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200420061
Status: Unutilized
Comment: 120 sq. ft., most recent use—obs. tower, off-site use only

Bldg. 5765
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65743–8944
Landholding Agency: Army
Property Number: 21200420062
Status: Unutilized
Comment: 800 sq. ft., most recent use—support bldg., off-site use only

New York

Bldgs. 1511–1518
U.S. Military Academy
Training Area
Highlands Co: Orange NY 10996–
Landholding Agency: Army
Property Number: 21200320160
Status: Unutilized
Comment: 2400 sq. ft. each, needs rehab, most recent use—barracks, off-site use only

Bldgs. 1523–1526
U.S. Military Academy
Training Area
Highlands Co: Orange NY 10996–
Landholding Agency: Army
Property Number: 21200320161
Status: Unutilized
Comment: 2400 sq. ft. each, needs rehab, most recent use—barracks, off-site use only

Bldgs. 1704–1705, 1721–1722
U.S. Military Academy
Training Area
Highlands Co: Orange NY 10996–
Landholding Agency: Army
Property Number: 21200320162
Status: Unutilized
Comment: 2400 sq. ft. each, needs rehab, most recent use—barracks, off-site use only

Bldg. 1723
U.S. Military Academy
Training Area
Highlands Co: Orange NY 10996–
Landholding Agency: Army
Property Number: 21200320163
Status: Unutilized
Comment: 2400 sq. ft., needs rehab, most recent use—day room, off-site use only

Bldgs. 1706–1709
U.S. Military Academy
Training Area
Highlands Co: Orange NY 10996–
Landholding Agemcy: Army
Property Number: 21200320164
Status: Unutilized
Comment: 2400 sq. ft. each, needs rehab, most recent use—barracks, off-site use only

Bldgs. 1731–1735
U.S. Military Academy
Traininng Area
Highlands Co: Orange NY 10996–
Landholding Agency: Army
Property Number: 21200320165
Status: Unutilized
Comment: 2400 sq. ft. each, needs rehab, most recent use—barracks, off-site use only

North Carolina

Bldgs. A2245, A2345
Fort Bragg
Ft. Bragg Co: Cumberland NC 28310–
Landholding Agency: Army
Property Number: 21200240084
Status: Excess
Comment: 3444 sq. ft. each, possible asbestos/lead paint, most recent use—vehicle maint. shop, off-site use only

Bldg. N4116

Fort Bragg
Ft. Bragg Co: Cumberland NC 28310–
Landholding Agency: Army
Property Number: 21200240087
Status: Excess
Comment: 3944 sq. ft., possible asbestos/lead paint, most recent use—community facility, off-site use only

Tennessee

Bldgs. 01551, 01552
Fort Campbell
Ft. Campbell Co: Montgomery TN 42223–
Landholding Agency: Army
Property Number: 21200230076
Status: Unutilized
Comment: 2052 sq. ft.

Texas

Bldgs. 4219, 4227
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220139
Status: Unutilized
Comment: 8056 and 10,500 sq. ft., most recent use—admin., off-site use only

Bldgs. 4229, 4230, 4231
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220140
Status: Unutilized
Comment: 9000 sq. ft., most recent use—hq. bldg., off-site use only

Bldgs. 4244, 4246
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220141
Status: Unutilized
Comment: 9000 sq. ft., most recent use—storage, off-site use only

Bldgs. 4260, 4261, 4262
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200220142
Status: Unutilized
Comment: 7680 sq. ft., most recent use—storage, off-site use only

Bldg. 00241
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200430067
Status: Unutilized
Comment: 1008 sq. ft.

Bldgs. 00242–00244
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200430068
Status: Unutilized
Comment: 1008 sq. ft. each, most recent use—instruction bldg.

Bldgs. 00245–00247
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200430069
Status: Unutilized
Comment: 1008 sq. ft. each, most recent use—instruction bldg.

Bldgs. 00248–00249
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200430070
Status: Unutilized
Comment: 1008 sq. ft. each, most recent use—instruction bldg.

Bldgs. 00250–00252
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200430071
Status: Unutilized
Comment: 1008 sq. ft. each, most recent use—instruction bldg.

Bldgs. 00253–00254
Fort Hood
Ft. Hood Co: Bell TX 76544–
Landholding Agency: Army
Property Number: 21200430072
Status: Unutilized
Comment: 1008 sq. ft. each, most recent use—instruction bldg.

Bldg. 00255
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440077
Status: Excess
Comment: 528 sq. ft., possible asbestos, off-site use only

3 Bldgs.
Fort Hood
Bell Co: TX 76544–
Location: 00256, 00257, 00258
Landholding Agency: Army
Property Number: 21200440078
Status: Excess
Comment: 2504 sq. ft., possible asbestos, most recent use—classroom, off-site use only

Bldgs. 00259, 00267
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440079
Status: Excess
Comment: 288 & 168 sq. ft., possible asbestos, most recent use—lunch room, off-site use only

Bldgs. 00268–00269
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440080
Status: Excess
Comment: 2304 sq. ft., possible asbestos, most recent use—instruction, off-site use only

3 Bldgs.
Fort Hood
Bell Co: TX 76544–
Location: 00716, 00717, 00718
Landholding Agency: Army
Property Number: 21200440081
Status: Excess
Comment: 3200 sq. ft., possible asbestos, most recent use—hq. bldg., off-site use only

Bldg. 00720
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440082
Status: Excess
Comment: 3200 sq. ft., possible asbestos, most recent use—shipping, off-site use only

Bldg. 00722
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440083
Status: Excess
Comment: 2665 sq. ft., possible asbestos, most recent use—dining, off-site use only

Bldg. 00728
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440084
Status: Excess
Comment: 2400 sq. ft., possible asbestos, most recent use—hq. bldg., off-site use only

Bldg. 00729
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440085
Status: Excess
Comment: 2400 sq. ft., possible asbestos, most recent use—auto aide, off-site use only

Bldgs. 01121, 01156
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440086
Status: Excess
Comment: 6728, 7020 sq. ft., possible asbestos, most recent use—general, off-site use only

Bldg. 04220
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440087
Status: Excess
Comment: 12,427 sq. ft., possible asbestos, most recent use—general, off-site use only

Bldgs. 04223–04226
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440088
Status: Excess
Comment: 9000 sq. ft., possible asbestos, most recent use—general, off-site use only

Bldg. 04280
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440089
Status: Excess
Comment: 96 sq. ft., possible asbestos, most recent use—scale house, off-site use only

Bldg. 04335
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440090
Status: Excess
Comment: 3378 sq. ft., possible asbestos, most recent use—general, off-site use only

6 Bldgs.
Fort Hood
Bell Co: TX 76544–

Location: 0441, 04412, 04413, 04414, 04418, 04432
Landholding Agency: Army
Property Number: 21200440091
Status: Excess
Comment: various sq. ft., possible asbestos, most recent use—hq. bldg., off-site use only

Bldg. 04450
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440092
Status: Excess
Comment: 5310 sq. ft., possible asbestos, most recent use—general, off-site use only

3 Bldgs.
Fort Hood
Bell Co: TX 76544–
Location: 04452, 04456, 04457
Landholding Agency: Army
Property Number: 21200440093
Status: Excess
Comment: 5310 sq. ft., possible asbestos, most recent use—hq. bldg., off-site use only

Bldg. 04465
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440094
Status: Excess
Comment: 5310 sq. ft., possible asbestos, most recent use—general, off-site use only

Bldgs. 04466–04467
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440095
Status: Excess
Comment: 5310 sq. ft., possible asbestos, most recent use—hq. bldg., off-site use only

Bldg. 04468
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440096
Status: Excess
Comment: 3100 sq. ft., possible asbestos, most recent use—misc., off-site use only

Bldg. 04473
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440097
Status: Excess
Comment: 3100 sq. ft., possible asbestos, most recent use—general, off-site use only

Bldgs. 04475–04476
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440098
Status: Excess
Comment: 3241 sq. ft., possible asbestos, most recent use—general, off-site use only

Bldg. 04477
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440099
Status: Excess
Comment: 3100 sq. ft., possible asbestos, most recent use—general, off-site use only

Bldg. 07002
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440100
Status: Excess
Comment: 2598 sq. ft., possible asbestos, most recent use—fire station, off-site use only

Bldg. 7002A
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440101
Status: Excess
Comment: 73 sq. ft., possible asbestos, most recent use—storage, off-site use only

Bldgs. 31007, 31009
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440102
Status: Excess
Comment: 139,693 sq. ft., possible asbestos, most recent use—barracks/operations, off-site use only

Bldg. 31008
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440103
Status: Excess
Comment: 17,936 sq. ft., possible asbestos, most recent use—dining, off-site use only

Bldg. 31011
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440104
Status: Excess
Comment: 23624 sq. ft., possible asbestos, most recent use—hq. bldg., off-site use only

Bldg. 57001
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440105
Status: Excess
Comment: 53,024 sq. ft., possible asbestos, most recent use—storage, off-site use only

Bldgs. 90039–90040
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440106
Status: Excess
Comment: 13,124 sq. ft., possible asbestos, most recent use—general, off-site use only

Bldgs. 90053–90054
Fort Hood
Bell Co: TX 76544–
Landholding Agency: Army
Property Number: 21200440107
Status: Excess
Comment: 884 & 206 sq. ft., possible asbestos, most recent use—storage, off-site use only

Virginia

Bldg. T2827
Fort Pickett
Blackstone Co: Nottoway VA 23824–
Landholding Agency: Army
Property Number: 21200320172
Status: Unutilized
Comment: 3550 sq. ft., presence of asbestos, most recent use—dining, off-site use only

Bldg. T2841
Fort Pickett
Blackstone Co: Nottoway VA 23824–
Landholding Agency: Army
Property Number: 21200320173
Status: Unutilized
Comment: 2950 sq. ft., presence of asbestos, most recent use—dining, off-site use only

Bldg. 03137
Fort Belvoir
Ft. Belvoir Co: Fairfax VA 22060–
Landholding Agency: Army
Property Number: 21200440110
Status: Unutilized
Comment: 2966 sq. ft., presence of asbestos, most recent use—airfield operations, off-site use only

Washington

Bldg. 05904
Fort Lewis
Ft. Lewis Co: Pierce WA 98433–9500
Landholding Agency: Army
Property Number: 21200240092
Status: Excess
Comment: 82 sq. ft., most recent use—guard shack, off-site use only

Unsuitable Properties

Buildings (by State)

Alabama

75 Bldgs.
Redstone Arsenal
Redstone Arsenal Co: Madison AL 35898-
Landholding Agency: Army
Property Number: 21200040001–21200040012, 21200120018, 21200220003–21200220004, 21200240007–21200240022, 21200330001–2120330004, 21200340011, 21200340095, 21200420068–21200420071, 21200440001
Status: Unutilized
Reason: Secured Area; Extensive deterioration

32 Bldgs., Fort Rucker
Ft. Rucker Co: Dale AL 36362
Landholding Agency: Army
Property Number: 219740006, 21200010010, 21200040013, 21200240002–21200240004, 21200420072–21200420073, 21200430006, 21200440002–21200440005, 21200510001
Status: Unutilized
Reason: Extensive deterioration

Bldg. 28152
Rucker
Hartford Co: Geneva AL 36344
Landholding Agency: Army
Property Number: 21200230002
Status: Unutilized
Reason: Extensive deterioration

Bldg. 01271
Fort McClellan
Ft. McClellan Co: Calhoun AL 36205–5000
Landholding Agency: Army
Property Number: 21200430004
Status: Unutilized
Reason: Extensive deterioration

Alaska

19 Bldgs., Fort Wainwright
Ft. Wainwright AK 99703
Landholding Agency: Army

Property Number: 219710090, 219710195–219710198, 219810002, 219810007, 21199920001, 21200340007–21200340010, 21200430001–21200430003
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured area; Floodway (Some are extensively deteriorated)

20 Bldgs., Fort Richardson
Ft. Richardson Co: AK 99505
Landholding Agency: Army
Property Number: 21200340001–21200340006
Status: Excess
Reason: Extensive deterioration

Arizona

32 Bldgs.
Navajo Depot Activity
Bellemont Co: Coconino AZ 86015–
Location: 12 miles west of Flagstaff, Arizona on I–40
Landholding Agency: Army
Property Number: 219014560–219014591
Status: Underutilized
Reason: Secured Area

10 properties: 753 earth covered igloos; above ground standard magazines
Navajo Depot Activity
Bellemont Co: Coconino AZ 86015–
Location: 12 miles west of Flagstaff, Arizona on I–40.
Landholding Agency: Army
Property Number: 219014592–219014601
Status: Underutilized
Reason: Secured Area

7 Bldgs.
Navajo Depot Activity
Bellemont Co: Coconino AZ 86015–5000
Location: 12 miles west of Flagstaff on I–40
Landholding Agency: Army
Property Number: 219030273, 219120177–219120181
Status: Unutilized
Reason: Secured Area

78 Bldgs.
Camp Navajo
Bellemont Co: AZ 86015
Landholding Agency: Army
Property Number: 21200140006–21200140010, 21200510002
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material; Secured Area (Most are extensively deteriorated)

Bldgs. 15348, 15344
Fort Huachuca
Ft. Huachuca Co: Cochise AZ 85613
Landholding Agency: Army
Property Number: 21200240024, 21200330005
Status: Excess
Reason: Extensive deterioration

Arkansas

189 Bldgs., Fort Chaffee
Ft. Chaffee Co: Sebastian AR 72905–5000
Landholding Agency: Army
Property Number: 219630019, 219630021, 219630029, 219640462–219640477, 21200110001–21200110017, 21200140011–21200140014
Status: Unutilized
Reason: Extensive deterioration

California

Bldg. 18
Riverbank Army Ammunition Plant
5300 Claus Road
Riverbank Co: Stanislaus CA 95367–
Landholding Agency: Army
Property Number: 219012554
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area

11 Bldgs., Nos. 2–8, 156, 1, 120, 181
Riverbank Army Ammunition Plant
Riverbank Co: Stanislaus CA 95367–
Landholding Agency: Army
Property Number: 219013582–219013588, 219013590, 219240444–219240446
Status: Underutilized
Reason: Secured Area

Bldgs. 13, 171, 178 Riverbank Ammun. Plant
5300 Claus Road
Riverbank Co: Stanislaus CA 95367–
Landholding Agency: Army
Property Number: 219120162–219120164
Status: Underutilized
Reason: Secured Area

40 Bldgs.
DDDRW Sharpe Facility
Tracy Co: San Joaquin CA 95331
Landholding Agency: Army
Property Number: 219610289, 21199930021, 21200030005–21200030015, 21200040015, 21200120029–21200120039, 21200130004, 21200240025–21200240030, 21200330007
Status: Unutilized
Reason: Secured Area

Bldgs. 29, 39, 73, 154, 155, 193, 204, 257
Los Alamitos Co: Orange CA 90720–5001
Landholding Agency: Army
Property Number: 219520040
Status: Unutilized
Reason: Extensive deterioration

10 Bldgs.
Sierra Army Depot
Herlong Co: Lassen CA 96113
Landholding Agency: Army
Property Number: 21199840015, 21199920033–21199920036, 21199940052–21199940056
Status: Underutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area

449 Bldgs.
Camp Roberts
Camp Roberts Co: San Obispo CA
Landholding Agency: Army
Property Number: 21199730014, 219820192–219820235
Status: Excess
Reason: Secured Area; Extensive deterioration

27 Bldgs.
Presidio of Monterey Annex
Seaside Co: Monterey CA 93944
Landholding Agency: Army
Property Number: 21199940051, 21200130005
Status: Unutilized
Reason: Extensive deterioration

46 Bldgs.
Fort Irwin
Ft. Irwin Co: San Bernardino CA 92310
Landholding Agency: Army
Property Number: 21199920037–21199920038, 21200030016–21200030018, 21200040014, 21200110018–21200110020, 21200130002–21200130003, 21200210001–21200210005, 21200240031–21200240033
Status: Unutilized
Reason: Secured Area; Extensive deterioration

6 Bldgs.
Fort Hunter Liggett
Jolon Co: Monterey CA 93928
Landholding Agency: Army
Property Number: 21200440006–21200440007
Status: Unutilized
Reason: Extensive deterioration

Bldg. 00636
Parks Reserve Forces
Dublin Co: Alameda CA 94568
Landholding Agency: Army
Property Number: 21200440008
Status: Unutilized
Reason: Extensive deterioration

Colorado

Bldgs. T–412, 431, 433
Rocky Mountain Arsenal
Commerce Co: Adams CO 80022–2180
Landholding Agency: Army
Property Number: 219320014–219320016
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

9 Bldgs. Fort Carson
Ft. Carson Co: El Paso CO 80913–5023
Landholding Agency: Army
Property Number: 219830024,21200130006–21200130009, 21200420161–21200420164
Status: Unutilized
Reason: Extensive deterioration (Some are within 2000 ft. of flammable or explosive material)

5 Bldgs.
Pueblo Chemical Depot
Pueblo CO 81006–9330
Landholding Agency: Army
Property Number: 21200030019–21200030021, 21200420165–21200420166
Status: Unutilized
Reason: Extensive deterioration

Georgia

Fort Stewart
Sewage Treatment Plant
Ft. Stewart Co: Hinesville GA 31314–
Landholding Agency: Army
Property Number: 219013922
Status: Unutilized
Reason: Sewage treatment

Facility 12304
Fort Gordon
Augusta Co: Richmond GA 30905–
Location: Located off Lane Avenue
Landholding Agency: Army
Property Number: 219014787
Status: Unutilized
Reason: Wheeled vehicle grease/inspection rack

59 Bldgs.
Fort Gordon
Augusta Co: Richmond GA 30905–
Landholding Agency: Army
Property Number: 219220269, 219410050–219410051, 219410071–219410072, 219410100, 219410109, 219630047–219630050, 219640011–219640023, 219830060, 21200210065, 21200210068,

21200220009, 21200230011, 21200230013, 21200440010–21200440014
Status: Unutilized
Reason: Extensive deterioration

40 Bldgs., Fort Benning
Ft. Benning Co: Muscogee GA 31905
Landholding Agency: Army
Property Number: 219610320, 219720017–219720019, 219810028, 219810030, 219810035, 219830073, 21199930034, 21200030026, 21200330008–21200330010, 21200410001–21200410010, 21200430011–21200430016, 21200440009, 21200510003
Status: Unutilized
Reason: Extensive deterioration

32 Bldgs.
Fort Gillem
Forest Park Co: Clayton GA 30050
Landholding Agency: Army
Property Number: 219620815, 21199920044–21199920050, 21200140016, 21200220011–21200220012, 21200230005, 21200340013–21200340016, 21200420074–21200420082
Status: Unutilized
Reason: Extensive deterioration; Secured Area

Bldg. P8121, Fort Stewart
Hinesville Co: Liberty GA 31314
Landholding Agency: Army
Property Number: 21199940060
Status: Unutilized
Reason: Extensive deterioration

2 Bldgs., Hunter Army Airfield
Savannah Co: Chatham GA 31409
Landholding Agency: Army
Property Number: 219830068, 21200430062
Status: Unutilized
Reason: Extensive deterioration

4 Bldgs., Fort McPherson
Ft. McPherson Co: Fulton GA 30330–5000
Landholding Agency: Army
Property Number: 21200040016–21200040018, 21200230004
Status: Unutilized
Reason: Secured Area

Hawaii

16 Bldgs.
Schofield Barracks
Wahiawa Co: Wahiawa HI 96786–
Landholding Agency: Army
Property Number: 219014836–219014837, 219030361, 21200410012
Status: Unutilized
Reason: Secured Area; (Most are extensively deteriorated)

4 Bldgs., Fort Shafter
Honolulu Co: HI 96819
Landholding Agency: Army
Property Number: 21200240034, 21200310001
Status: Unutilized
Reason: Extensive deterioration

130 Tunnels
Aliamanu
Honolulu Co: HI 96818
Landholding Agency: Army
Property Number: 21200440015–21200440017
Status: Unutilized
Reason: Contamination

Illinois

5 Bldgs.
Rock Island Arsenal
Rock Island Co: Rock Island IL 61299–5000
Landholding Agency: Army
Property Number: 219110106, 219620427, 219620428, 21200140043–21200140044
Status: Unutilized
Reason: Some are in a secured area; Some are extensively deteriorated; Some are within 2000 ft. of flammable or explosive material

15 Bldgs.
Charles Melvin Price Support Center
Granite City Co: Madison IL 62040
Landholding Agency: Army
Property Number: 219820027, 21199930042–21199930053
Status: Unutilized
Reason: Secured Area; Floodway; Extensive deterioration

Bldgs. 111, 145
Col. Schulstad Memorial USARC
Arlington Heights Co: Cook IL 60005
Landholding Agency: Army
Property Number: 21200320012
Status: Unutilized
Reason: Extensive deterioration

Indiana

130 Bldgs.
Newport Army Ammunition Plant
Newport Co: Vermillion IN 47966–
Landholding Agency: Army
Property Number: 219011584, 219011586–219011587, 219011589–219011590, 219011592–219011627, 219011629–219011636, 219011638–219011641, 219210149, 219430336, 219430338, 219530079–219530096, 219740021–219740026, 219820031–219820032, 21199920063, 21200330015–21200330016, 21200440019
Status: Unutilized
Reason: Secured Area (Some are extensively deteriorated.)

2 Bldgs.
Atterbury Reserve Forces Training Area
Edinburgh Co: Johnson IN 46124–1096
Landholding Agency: Army
Property Number: 219230030–219230031
Status: Unutilized
Reason: Extensive deterioration

Bldgs. 300, 00112, 00123
Fort Benjamin Harrison
Indianapolis Co: Marion IN 46216
Landholding Agency: Army
Property Number: 21200320011, 21200430017
Status: Unutilized
Reason: Contamination

Iowa

115 Bldgs.
Iowa Army Ammunition Plant
Middletown Co: Des Moines IA 52638–
Landholding Agency: Army
Property Number: 219012605–219012607, 219012609, 219012611, 219012613, 219012620, 219012622, 219012624, 219013706–219013738, 219120172–219120174, 219440112–219440158, 219520002, 219520070, 219740027, 21200220022, 21200230019–21200230023, 21200330012–21200330014, 21200340017, 21200420083, 21200430018, 21200440018, 21200510004–21200510006
Status: Unutilized
Reason: (Many are in a Secured Area) (Most are within 2000 ft. of flammable or explosive material.)

27 Bldgs., Iowa Army Ammunition Plant
Middletown Co: Des Moines IA 52638
Landholding Agency: Army
Property Number: 219230005–219230029, 219310017, 219340091
Status: Unutilized
Reason: Extensive deterioration

Kansas

37 Bldgs.
Kansas Army Ammunition Plant
Production Area
Parsons Co: Labette KS 67357–
Landholding Agency: Army
Property Number: 219011909–219011945
Status: Unutilized
Reason: Secured Area (Most are within 2000 ft. of flammable or explosive material)

121 Bldgs.
Kansas Army Ammunition Plant
Parsons Co: Labette KS 67357–
Landholding Agency: Army
Property Number: 219620518–219620638
Status: Unutilized
Reason: Secured Area

Bldg. 00166
Fort Riley
Ft. Riley Co: Riley KS 66442
Landholding Agency: Army
Property Number: 21200310007
Status: Unutilized
Reason: Extensive deterioration

19 Bldgs.
Ft. Leavenworth
Ft. Leavenworth Co: KS 66027
Landholding Agency: Army
Property Number: 21200440020–21200440024
Status: Unutilized
Reason: Extensive deterioration

Kentucky

Bldg. 126
Lexington-Blue Grass Army Depot
Lexington Co: Fayette KY 40511–
Location: 12 miles northeast of Lexington, Kentucky.
Landholding Agency: Army
Property Number: 219011661
Status: Unutilized
Reason: Secured Area; Sewage treatment facility

Bldg. 12
Lexington-Blue Grass Army Depot
Lexington Co: Fayette KY 40511–
Location: 12 miles Northeast of Lexington Kentucky
Landholding Agency: Army
Property Number: 219011663
Status: Unutilized
Reason: Industrial waste treatment plant

32 Bldgs., Fort Knox
Ft. Knox Co: Hardin KY 40121–
Landholding Agency: Army
Property Number: 21200130028–21200130029, 21200440025–21200440026, 21200510007–21200510009
Status: Unutilized
Reason: Extensive deterioration

45 Bldgs., Fort Campbell
Ft. Campbell Co: Christian KY 42223
Landholding Agency: Army

Property Number: 21200110030–21200110049, 21200140048, 21200140053, 21200220029, 21200230029–21200230030, 21200320018, 21200330018–21200330022, 21200420088, 21200510010
Status: Unutilized
Reason: Extensive deterioration

Louisiana

528 Bldgs.
Louisiana Army Ammunition Plant
Doylin Co: Webster LA 71023–
Landholding Agency: Army
Property Number: 219011714–219011716, 219011735–219011737, 219012112, 219013863–219013869, 219110131, 219240138–219240147, 219420332, 219610049–219610263, 219620002–219620200, 219620749–219620801, 219820047–219820078
Status: Unutilized
Reason: Secured Area (Most are within 2000 ft. of flammable or explosive material) (Some are extensively deteriorated)

38 Bldgs., Fort Polk
Ft. Polk Co: Vernon Parish LA 71459–7100
Landholding Agency: Army
Property Number: 21199920070, 21199920078, 21199940074, 21199940075, 21200120058, 21200130030–21200130043
Status: Unutilized
Reason: Extensive deterioration (Some are in Floodway.)

Maryland

90 Bldgs.
Aberdeen Proving Ground
Aberdeen City Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 219012610, 219012638–219012642, 219012658–219012662, 219014711, 219610489–219610490, 219730077, 219810076–219810112, 219820090–219820096, 21200120059–21200120060, 21200410017–21200410032, 21200420097–21200420103, 21200440027–21200440030, 21200510011–21200510013
Status: Unutilized
Reason: Most are in a secured area. (Some are within 2000 ft. of flammable or explosive material) (Some are in a floodway) (Some are extensively deteriorated)

61 Bldgs. Ft. George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–
Landholding Agency: Army
Property Number: 219810065,21199910019, 21199940084, 21200140059–21200140060, 21200240046–21200240051, 21200410014–21200410016, 21200510017–21200510019
Status: Unutilized
Reason: Extensive deterioration

Bldg. 00211, Curtis Bay Ordnance Depot
Baltimore Co: MD 21226
Landholding Agency: Army
Property Number: 21200320024
Status: Unutilized
Reason: Extensive deterioration

6 Bldgs., Fort Detrick
Frederick Co: MD 21702
Landholding Agency: Army
Property Number: 21200430019–21200430020, 21200510014–21200510016
Status: Unutilized
Reason: Secured Area

Massachusetts

Bldg. 3462, Camp Edwards
Massachusetts Military Reservation
Bourne Co: Barnstable MA 024620–5003
Landholding Agency: Army
Property Number: 219230095
Status: Unutilized
Reason: Secured Area; Extensive deterioration

Bldg. 1211, Camp Edwards
Massachusetts Military Reservation
Bourne Co: Barnstable MA 02462–5003
Landholding Agency: Army
Property Number: 219310020
Status: Unutilized
Reason: Secured Area

Facility No. 0G001
LTA Granby
Granby Co: Hampshire MA
Landholding Agency: Army
Property Number: 219810062
Status: Unutilized
Reason: Extensive deterioration

5 Bldgs.
Devens RFTA
Devens Co: MA 01432–4429
Landholding Agency: Army
Property Number: 21200340019–21200340021
Status: Unutilized
Reason: Extensive deterioration

6 Bldgs.
Fera USARC
Danvers Co: Essex MA 01923–1121
Landholding Agency: Army
Property Number: 21200420089–21200420092
Status: Unutilized
Reason: Extensive deterioration

Michigan

Bldgs. 5755–5756
Newport Weekend Training Site
Carleton Co: Monroe MI 48166
Landholding Agency: Army
Property Number: 219310060–219310061
Status: Unutilized
Reason: Secured Area; Extensive deterioration

31 Bldgs.
Fort Custer Training Center
2501 26th Street
Augusta Co: Kalamazoo MI 49102–9205
Landholding Agency: Army
Property Number: 21200220058–21200220062, 21200410036–21200410042
Status: Unutilized
Reason: Extensive deterioration

39 Bldgs.
US Army Garrison-Selfridge
Macomb Co: MI 48045
Landholding Agency: Army
Property Number: 21200420093, 21200510020–21200510023
Status: Unutilized
Reason: Secured Area

4 Bldgs.
Poxin USAR Center
Southfield Co: Oakland MI 48034
Landholding Agency: Army
Property Number: 21200330026–21200330027, 21200420095
Status: Unutilized
Reason: Extensive deterioration

8 Bldgs.
Grayling Army Airfield
Grayling Co: Crawford MI 49739
Landholding Agency: Army
Property Number: 21200410034–21200410035
Status: Excess
Reason: Extensive deterioration

Bldg. 001, Crabble USARC
Saginaw MI 48601–4099
Landholding Agency: Army
Property Number: 21200420094
Status: Unutilized
Reason: Extensive deterioration

Bldg. 00714
Selfridge Air Natl Guard Base
Macomb Co: MI 48045
Landholding Agency: Army
Property Number: 21200440032
Status: Unutilized
Reason: Extensive deterioration

Minnesota

160 Bldgs.
Twin Cities Army Ammunition Plant
New Brighton Co: Ramsey MN 55112–
Landholding Agency: Army
Property Number: 219120166, 219210014–219210015, 219220227–219220235, 219240328, 219310056, 219320152–219320156, 219330096–219330106, 219340015, 219410159–219410189, 219420198–219420283, 219430060–219430064, 21200130053–21200130054
Status: Unutilized
Reason: Secured Area (Most are within 2000 ft. of flammable or explosive material.) (Some are extensively deteriorated)

Missouri

83 Bldgs.
Lake City Army Ammo. Plant
Independence Co: Jackson MO 64050–
Landholding Agency: Army
Property Number: 219013666–219013669, 219530134, 219530136, 21199910023–21199910035, 21199920082, 21200030049
Status: Unutilized
Reason: Secured Area (Some are within 2000 ft. of flammable or explosive material)

St. Louis Army Ammunition Plant
4800 Goodfellow Blvd.
St. Louis Co: St. Louis MO 63120–1798
Landholding Agency: Army
Property Number: 219120067–219120068, 219610469–219610475
Status: Unutilized
Reason: Secured Area (Some are extensively deteriorated.)

21 Bldgs.
Fort Leonard Wood
Ft. Leonard Wood Co: Pulaski MO 65473–5000
Landholding Agency: Army
Property Number: 219430075, 21199910020–21199910021, 21200320025, 21200330028–21200330031, 21200430029
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material (Some are extensively deteriorated.)

Bldg. P4122
U.S. Army Reserve Center
St. Louis Co: St. Charles MO 63120–1794
Landholding Agency: Army
Property Number: 21200240055

Status: Unutilized
Reason: Extensive deterioration

Bldgs. P4074, P4072, P4073
St. Louis Ordnance Plant
St. Louis Co: St. Charles MO 63120–1794
Landholding Agency: Army
Property Number: 21200310019
Status: Unutilized
Reason: Extensive deterioration

Montana

Bldg. P0516, Fort Harrison
Ft. Harrison Co: Lewis/Clark MT 59636
Landholding Agency: Army
Property Number: 21200420104
Status: Excess
Reasons: Secured Area; Extensive deterioration

Nevada

Bldg. 292
Hawthorne Army Ammunition Plant
Hawthorne Co: Mineral NV 89415–
Landholding Agency: Army
Property Number: 219013614
Status: Unutilized
Reason: Secured Area

39 Bldgs.
Hawthorne Army Ammunition Plant
Hawthorne Co: Mineral NV 89415–
Landholding Agency: Army
Property Number: 219012013, 219013615–219013643
Status: Underutilized
Reason: Secured Area (Some within airport runway clear zone; many within 2000 ft. of flammable or explosive material)

Group 101, 34 Bldgs.
Hawthorne Army Ammunition Plant
Hawthorne Co: Mineral NV 89415–0015
Landholding Agency: Army
Property Number: 219830132
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area

New Jersey

165 Bldgs., Picatinny Arsenal
Dover Co: Morris NJ 07806–5000
Landholding Agency: Army
Property Number: 219010444–219010474, 219010639–219010664, 219010680–219010715, 219012428, 219012430, 219012433–219012465, 219012469, 219012475, 219012765, 219014306, 219014311, 219014317,219140617, 219230123, 219420006, 219530147, 219540005, 219540007, 219740113–219740127, 21199940094–21199940099, 21200130057–21200130063, 21200220063, 21200230072–21200230075, 21200330047–21200330063, 21200410043–21200410044
Status: Excess
Reason: Secured Area (Most are within 2000 ft. of flammable or explosive material.) (Some are extensively deteriorated and in a floodway)

7 Bldgs., Ft. Monmouth
Ft. Monmouth Co: NJ 07703
Landholding Agency: Army
Property Number: 21200430030, 21200440033, 21200510025–21200510027
Status: Unutilized
Reason: Extensive deterioration

14 Bldgs., Fort Dix
Ft. Dix Co: Burlington NJ 08640–5506
Landholding Agency: Army
Property Number: 21200330037–21200330046, 21200420109–21200420111, 21200510024
Status: Unutilized
Reason: Extensive deterioration

New Mexico

164 Bldgs.
White Sands Missile Range
Dona Ana Co: NM 88002
Landholding Agency: Army
Property Number: 21200410045–21200410049, 21200440034–21200440045
Status: Excess
Reason: Secured Area

New York

Bldg. 12
Watervliet Arsenal
Watervliet NY
Landholding Agency: Army
Property Number: 219730099
Status: Unutilized
Reason: Extensive deterioration; Secured Area

13 Bldgs., Youngstown Training Site
Youngstown Co: Niagara NY 14131
Landholding Agency: Army
Property Number: 21200220064–21200220069
Status: Unutilized
Reason: Extensive deterioration

Bldgs. 1716, 3014 U.S. Military Academy
West Point Co: NY 10996
Landholding Agency: Army
Property Number: 21200330064, 21200410050
Status: Unutilized
Reason: Extensive deterioration

52 Bldgs., Fort Drum
Ft. Drum Co: Jefferson NY 13602
Landholding Agency: Army
Property Number: 21200340027–21200340029, 21200410051, 21200420112–21200420128, 21200440046
Status: Unutilized
Reason: Extensive deterioration

Bldg. 108
Fredrick J ILL, Jr. USARC
Bullville Co: Orange NY 10915–0277
Landholding Agency: Army
Property Number: 21200510028
Status: Unutilized
Reason: Secured Area

Bldgs. 107, 112, 113
Kerry P. Hein USARC
NY058
Shoreham Co: Suffolk NY 11778–9999
Landholding Agency: Army
Property Number: 21200510054
Status: Excess
Reason: Secured Area

North Carolina

87 Bldgs. Fort Bragg
Ft. Bragg Co: Cumberland NC 28307
Landholding Agency: Army
Property Number: 219640074, 219710102–219710111, 219710224, 219810167, 21200040035, 21200140064, 21200340031–21200340045, 21200410056, 21200420130, 21200430042, 21200440047–21200440051
Status: Unutilized
Reason: Extensive deterioration

3 Bldgs., Military Ocean Terminal
Southport Co: Brunswick NC 28461–5000
Landholding Agency: Army
Property Number: 219810158–219810160, 21200330032
Status: Unutilized
Reason: Secured Area

North Dakota

Bldgs. 440, 455, 456, 3101, 3110
Stanley R. Mickelsen
Nekoma Co: Cavalier ND 58355
Landholding Agency: Army
Property Number: 21199940103–21199940107
Status: Unutilized
Reason: Extensive deterioration

Ohio

181 Bldgs.
Ravenna Army Ammunition Plant
Ravenna Co: Portage OH 44266–9297
Landholding Agency: Army
PropertyNumber: 21199840069–21199840104, 21200240064, 21200420131–21200420132
Status: Unutilized
Reason: Secured Area

7 Bldgs.
Lima Army Tank Plant
Lima OH 45804–1898
Landholding Agency: Army
Property Number: 219730104–219730110
Status: Unutilized
Reason: Secured Area

Oklahoma

3 Bldgs., Fort Sill
Lawton Co: Comanche OK 73503–
Landholding Agency: Army
Property Number: 219510023, 21200330065, 21200430043
Status: Unutilized
Reason: Extensive deterioration

Bldgs. MA050, MA070
Regional Training Institute
Oklahoma City Co: OK 73111
Landholding Agency: Army
Property Number: 21200440052
Status: Unutilized
Reason: Extensive deterioration

Bldgs. GRM03, GRM24, GRM26, GRM34
Camp Gruber Training Site
Braggs Co: OK 74423
Landholding Agency: Army
Property Number: 21200510029–21200510032
Status: Unutilized
Reason: Extensive deterioration

20 Bldgs.
McAlester Army Ammo Plant
McAlester Co: Pittsburg OK 74501
Landholding Agency: Army
Property Number: 21200510033–21200510039
Status: Excess
Reason: Secured Area

Oregon

11 Bldgs.
Tooele Army Depot
Umatilla Depot Activity
Hermiston Co: Morrow/Umatilla OR 97838–
Landholding Agency: Army
Property Number: 219012174–219012176, 219012178–219012179, 219012190–

219012191, 219012197–219012198, 219012217, 219012229
Status: Underutilized
Reason: Secured Area

34 Bldgs.
Tooele Army Depot
Umatilla Depot Activity
Hermiston Co: Morrow/Umatilla OR 97838–
Landholding Agency: Army
Property Number: 219012177,219012185–219012186,219012189, 219012195–219012196,219012199–219012205,219012207–219012208, 219012225,219012279,219014304–219014305,219014782, 219030362–219030363, 219120032, 21199840108–21199840110, 21199920084–21199920090
Status: Unutilized
Reason: Secured Area

Pennsylvania

23 Bldgs., Fort Indiantown Gap
Annville Co: Lebanon PA 17003–5011
Landholding Agency: Army
Property Number: 219810183–219810190
Status: Unutilized
Reason: Extensive deterioration

2 Bldgs.
Defense Distribution Depot
New Cumberland Co: York PA 17070–5001
Landholding Agency: Army
Property Number: 21200430044, 21200510041
Status: Unutilized
Reason: Secured Area (Some are extensively deteriorated)

8 Bldgs., Tobyhanna Army Depot
Tobyhanna Co: Monroe PA 18466
Landholding Agency: Army
Property Number: 21200330068, 21200440053–21200440054, 21200510040
Status: Unutilized
Reason: Extensive deterioration

Bldg. 01003, C.E. Kelly Support Facility
Neville Island Co: Allegheny PA 15225
Landholding Agency: Army
Property Number: 21200330069
Status: Unutilized
Reason: Extensive deterioration

28 Bldgs.
Letterkenny Army Deport
Chambersburg Co: Franklin PA 17201
Landholding Agency: Army
Property Number: 21200420134–21200420144, 21200430045–21200430051
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

Bldgs. 00014, 00033, 00044
CE Kelly Support Facility
Oakdale Co: Allegheny PA 15071
Landholding Agency: Army
Property Number: 21200420153–21200420155
Status: Unutilized
Reason: Secured Area

4 Bldgs., Carlisle Barracks
Cumberland Co: PA 17013
Landholding Agency: Army
Property Number: 21200440055–21200440056
Status: Excess
Reason: Extensive deterioration

Puerto Rico

105 Bldgs., Fort Buchanan
Guaynabo Co: PR 00934
Landholding Agency: Army
Property Number: 21200330077–21200330092, 21200340052–21200340055, 21200420156–21200420160
Status: Unutilized
Reason: Secured Area (Some are extensively deteriorated)

South Carolina

40 Bldgs., Fort Jackson
Ft. Jackson Co: Richland SC 29207
Landholding Agency: Army
Property Number: 219440237, 219440239, 219620312, 219620317, 219620348, 219620351, 219640138–219640139, 21199640148–21199640149, 219720095, 219720097, 219730130, 219730132, 219730145–219730157, 219740138, 219820102–219820111, 219830139–219830157
Status: Unutilized
Reason: Extensive deterioration

Tennessee

74 Bldgs.
Holston Army Ammunition Plant
Kingsport Co: Hawkins TN 61299–6000
Landholding Agency: Army
Property Number: 219012304–219012309, 219012311–219012312, 219012314, 219012316–219012317, 219012328, 219012330, 219012332, 219012334, 219012337, 219013790, 219140613, 219440212–219440216, 219510025–219510027, 21200230035, 21200310040, 21200320054–21200320073, 21200340056, 21200510042
Status: Unutilized
Reason: Secured Area (Some are within 2000 ft. of flammable or explosive material)

38 Bldgs.
Milan Army Ammunition Plant
Milan Co: Gibson TN 38358
Landholding Agency: Army
Property Number: 219240447–219240449, 21200440059–21200440061
Status: Unutilized
Reason: Secured Area (Some are extensively deteriorated)

Bldg. Z–183A
Milan Army Ammunition Plant
Milan Co: Gibson TN 38358
Landholding Agency: Army
Property Number: 219240783
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material

48 Bldgs.
Fort Campbell
Ft. Campbell Co: Montgomery TN 42223
Landholding Agency: Army
Property Number: 21200220023, 21200230033, 21200240065,21200320046, 21200330094–21200330100, 21200420145, 21200430052–2100430055, 21200440057–21200440058, 21200510043
Status: Unutilized
Reason: Extensive deterioration

Texas

20 Bldgs.
Lone Star Army Ammunition Plant
Highway 82 West
Texarkana Co: Bowie TX 75505–9100
Landholding Agency: Army
Property Number: 219012524, 219012529, 219012533, 219012536, 219012539–219012540, 219012542, 219012544–219012545, 219030337–219030345
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area

154 Bldgs.
Longhorn Army Ammunition Plant
Karnack Co: Harrison TX 75661–
Location: State highway 43 north
Landholding Agency: Army
Property Number: 219620827, 21200340062–21200340073
Status: Unutilized
Reason: Secured Area (Most are within 2000 ft. of flammable or explosive material)

16 Bldgs., Red River Army Depot
Texarkana Co: Bowie TX 75507–5000
Landholding Agency: Army
Property Number: 219420315–219420327, 219430095–219430097
Status: Unutilized
Reason: Secured Area (Some are extensively deteriorated)

85 Bldgs. Fort Bliss
El Paso Co: El Paso TX 79916
Landholding Agency: Army
Property Number: 219730160–219730186, 219830161–219830197, 21200310044, 21200320079, 21200340059
Status: Unutilized
Reason: Extensive deterioration

8 Bldgs.
Grand Prairie Reserve Complex
Grand Prairie Co: Tarrant TX 75050
Landholding Agency: Army
Property Number: 21200330101–21200330103, 21200340061, 21200420152
Status: Unutilized
Reason: Secured Area

6 Bldgs., Fort Hood
Ft. Hood Co: Bell TX 76544
Landholding Agency: Army
Property Number: 21200420146–21200420147
Status: Unutilized
Reason: Extensive deterioration

Utah

26 Bldgs.
Tooele Army Depot
Tooele Co: Tooele UT 84074–5008
Landholding Agency: Army
Property Number: 219012166, 219012751, 21200440063–21200440065
Status: Unutilized
Reason: Secured Area

Bldg. 9307
Dugway Proving Ground
Dugway Co: Toole UT 84022–
Landholding Agency: Army
Property Number: 219013997
Status: Underutilized
Reason: Secured Area

Bldgs. 3102, 5145, 8030
Deseret Chemical Depot
Tooele UT 84074
Landholding Agency: Army
Property Number: 219820119–219820121
Status: Unutilized
Reason: Secured Area; Extensive deterioration

Virginia

348 Bldgs.
Radford Army Ammunition Plant
Radford Co: Montgomery VA 24141–
Landholding Agency: Army
Property Number: 219010833, 219010836, 219010842, 219010844, 219010847–219010890, 219010892–219010912, 219011521–219011577, 219011581–219011583, 219011585, 219011588, 219011591, 219013559–219013570, 219110142–219110143, 219120071, 219140618–219140633, 219220210–219220218, 219230100–219230103, 219240324, 219440219–219440225, 219510031–219510033, 219520037, 219520052, 219530194, 219610607–219610608, 219830223–219830267, 21200020079–21200020081, 21200230038, 21200240071–21200240072, 21200510045–21200510046
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area (Some are extensively deteriorated)

13 Bldgs.
Radford Army Ammunition Plant
Radford Co: Montgomery VA 24141–
Landholding Agency: Army
Property Number: 219010834–219010835, 219010837–219010838, 219010840–219010841, 219010843, 219010845–219010846, 219010891, 219011578–219011580
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Latrine, detached structure

36 Bldgs.
U.S. Army Combined Arms Support Command
Fort Lee Co: Prince George VA 23801–
Landholding Agency: Army
Property Number: 219240107, 219330210, 219330225–219330228, 219610597, 219620866–219620876, 219630115, 219740156, 219830208–219830210, 21199940130, 21200110064, 21200340074, 21200430058–21200430060, 21200510050
Status: Unutilized
Reason: Extensive deterioration (Some are in a secured area.)

56 Bldgs.
Red Water Field Office
Radford Army Ammunition Plant
Radford VA 24141
Landholding Agency: Army
Property Number: 219430341–219430396
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area

84 Bldgs.
Fort A.P. Hill
Bowling Green Co: Caroline VA 22427
Landholding Agency: Army
Property Number: 21200310058–21200310060, 21200410068–21200410077, 21200430057, 21200510051
Status: Unutilized
Reason: Secured Area; Extensive deterioration

11 Bldgs.
Fort Belvoir
Ft. Belvoir Co: Fairfax VA 22060–5116
Landholding Agency: Army
Property Number: 21199910050–21199910051, 21199920107, 21199940117–21199940120, 21200030063–21200030064, 21200130075–21200130077
Status: Unutilized
Reason: Extensive deterioration

6 Bldgs., Fort Eustis
Ft. Eustis Co. VA 23604
Landholding Agency: Army
Property Number: 21200210025–21200210026
Status: Unutilized
Reason: Extensive deterioration

Bldgs. 448, 501 Fort Myer
Ft. Myer Co: Arlington VA 22211–1199
Landholding Agency: Army
Property Number: 21200010069, 21200510044
Status: Underutilized
Reason: Extensive deterioration

5 Bldgs.
Fort Monroe
Ft. Monroe Co: VA 23651
Landholding Agency: Army
Property Number: 21200410067, 21200430056, 21200510047–21200510049
Status: Excess
Reason: Extensive deterioration

51 Bldgs.
Fort Pickett
Blackstone Co: Nottoway VA 23824
Landholding Agency: Army
Property Number: 21200220087–21200220092, 21200320080–21200320087
Status: Unutilized
Reason: Extensive deterioration

Bldg. 00723, Fort Story
Ft. Story Co: Princess Ann VA 23459
Landholding Agency: Army
Property Number: 21200310046
Status: Unutilized
Reason: Extensive deterioration

Washington

663 Bldgs., Fort Lewis
Ft. Lewis Co: Pierce WA 98433–5000
Landholding Agency: Army
Property Number: 219610006, 219610009–219610010, 219610045–219610046, 219620512-219620517, 219640193, 219720142–219720151, 219810205–219810242, 219820132, 21199910064–21199910078, 21199920125–21199920174, 21199930080–21199930104, 21199940134, 21200120068, 21200140072–21200140073, 21200210075, 21200220097, 21200330104–21200330106, 21200430061
Status: Unutilized
Reason: Secured Area; Extensive deterioration

Bldg. HBC07, Fort Lewis
Huckleberry Creek Mountain Training Site
Co: Pierce WA
Landholding Agency: Army
Property Number: 219740166
Status: Unutilized
Reason: Extensive deterioration

Bldg. 415, Fort Worden
Port Angeles Co: Clallam WA 98362
Landholding Agency: Army
Property Number: 21199910062
Status: Excess
Reason: Extensive deterioration

Bldg. U515A, Fort Lewis
Ft. Lewis Co: Pierce WA 98433
Landholding Agency: Army
Property Number: 21199920124
Status: Excess
Reason: gas chamber

Bldgs. 02401, 02402
Vancouver Barracks Cemetery
Vancouver Co: WA 98661
Landholding Agency: Army
Property Number: 21200310048
Status: Unutilized
Reason: Extensive deterioration

4 Bldgs. Renton USARC
Renton Co: WA 980058
Landholding Agency: Army
Property Number: 21200310049
Status: Unutilized
Reason: Extensive deterioration

Wisconsin

5 Bldgs.
Badger Army Ammunition Plant
Baraboo Co: Sauk WI 53913–
Landholding Agency: Army
Property Number: 219011209–219011212, 219011217
Status: Underutilized
Reason: Within 2000 ft. of flammable or explosive material; Friable asbestos; Secured Area

153 Bldgs.
Badger Army Ammunition Plant
Baraboo Co: Sauk WI 53913–
Landholding Agency: Army
Property Number: 219011104, 219011106, 219011108–219011113, 219011115–219011117, 219011119–219011120, 219011122–219011139, 219011141–219011142, 219011144, 219011148–219011208, 219011213–219011216, 219011218–219011234, 219011236, 219011238, 219011240, 219011242, 219011244, 219011247, 219011249, 219011251, 219011256, 19011259, 219011263, 219011265, 219011268, 219011270, 219011275, 219011277, 219011280, 219011282, 219011284, 219011286, 219011290, 219011293, 219011295, 219011297, 219011300, 219011302, 219011304–219011311, 219011317, 219011319–219011321, 219011323
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Friable asbestos; Secured Area

4 Bldgs.
Badger Army Ammunition Plant
Baraboo Co: Sauk WI
Landholding Agency: Army
Property Number: 219013871–219013873, 219013875
Status: Underutilized
Reason: Secured Area

906 Bldgs.
Badger Army Ammunition Plant
Baraboo Co: Sauk WI
Landholding Agency: Army
Property Number: 219013876–219013878, 219210097–219210099, 219220295–219220311, 219510065,219510067, 219510069–219510077, 219740184–219740271, 21200020083–21200020155, 21200240074–21200240080
Status: Unutilized

Reason: (Most are in a secured area) (Most are within 2000 ft. of flammable or explosive material (Some are extensively deteriorated)

Land (by State)

Indiana

Newport Army Ammunition Plant
East of 14th St. & North of S. Blvd.
Newport Co: Vermillion IN 47966–
Landholding Agency: Army
Property Number: 219012360
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area

Maryland

Carroll Island, Graces Quarters
Aberdeen Proving Ground
Edgewood Area
Aberdeen City Co: Harford MD 21010–5425
Landholding Agency: Army
Property Number: 219012630, 219012632
Status: Underutilized
Reason: Floodway; Secured Area

15 acres, Fort Meade
Ft. Meade Co: MD 20755–5115
Landholding Agency: Army
Property Number: 21200440031
Status: Unutilized
Reason: Secured Area

Minnesota

Portion of R.R. Spur
Twin Cities Army Ammunition Plant
New Brighton Co: Ramsey MN 55112
Landholding Agency: Army
Property Number: 219620472
Status: Unutilized
Reason: landlocked

New Jersey

Land
Armament Research Development & Eng. Center
Route 15 North
Picatinny Arsenal Co: Morris NJ 07806–
Landholding Agency: Army
Property Number: 219013788
Status: Unutilized
Reason: Secured Area

Spur Line/Right of Way
Armament Rsch., Dev., & Eng. Center
Picatinny Arsenal Co: Morris NJ 07806–5000
Landholding Agency: Army
Property Number: 219530143
Status: Unutilized
Reason: Floodway

2.0 Acres, Berkshire Trail
Armament Rsch., Dev., & Eng. Center
Picatinny Arsenal Co: Morris NJ 07806–5000
Landholding Agency: Army
Property Number: 21199910036
Status: Underutilized
Reasons: Within 2000 ft. of flammable or explosive material; Secured Area

Texas

Land—Approx. 50 acres
Lone Star Army Ammunition Plant
Texarkana Co: Bowie TX 75505–9100
Landholding Agency: Army
Property Number: 219420308
Status: Unutilized
Reason: Secured Area

[FR Doc. 05–1873 Filed 2–3–05; 8:45 am]

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Federal Register

Friday,
February 4, 2005

Part VII

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2520

Annual Funding Notice for Multiemployer Defined Benefit Pension Plans; Proposed Rule

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2520

RIN 1210–AB00

Annual Funding Notice for Multiemployer Defined Benefit Pension Plans

AGENCY: Employee Benefits Security Administration, DOL.

ACTION: Proposed rule.

SUMMARY: This document contains a proposed regulation that, upon adoption, would implement the notice requirement in section 101(f) of the Employee Retirement Income Security Act of 1974. Section 103 of the Pension Funding Equity Act of 2004 (PFEA '04) amended section 101 of ERISA by adding a new subsection (f), which requires the administrator of a multiemployer defined benefit plan to provide participants, beneficiaries, and certain other parties, including the Pension Benefit Guaranty Corporation, with an annual funding notice indicating, among other things, whether the plan's funded current liability percentage is at least 100 percent. This document also contains a model notice that may be used by plan administrators in discharging their duties under section 101(f). This proposed regulation, upon adoption, will affect plan administrators, participants, and beneficiaries of multiemployer defined benefit pension plans, as well as labor organizations representing such participants or beneficiaries and employers that have an obligation to contribute under such plans.

DATES: Written comments on the proposed regulation should be received by the Department of Labor on or before March 7, 2005. *See* ''C. Request for Comments,'' in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: Comments should be addressed to the Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5669, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attn: PFEA '04 Project. Comments also may be submitted electronically to *e-ORI@dol.gov*. All comments received will be available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Stephanie L. Ward, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

Section 103(a) of the Pension Funding Equity Act of 2004, Pub. L. 108–218 (PFEA '04), which was enacted on April 10, 2004, added section 101(f) to the Employee Retirement Income Security Act of 1974, as amended (ERISA or the Act). Section 101(f) provides that the administrator of a defined benefit plan which is a multiemployer plan shall for each plan year furnish a plan funding notice to each plan participant and beneficiary, to each labor organization representing such participants or beneficiaries, to each employer that has an obligation to contribute under the plan, and to the Pension Benefit Guaranty Corporation. Section 103(b) of PFEA '04 amended section 502(c)(1) of ERISA to provide that any administrator who fails to meet the requirements of section 101(f) with respect to a participant or beneficiary may, in a court's discretion, be personally liable to such participant or beneficiary in the amount of up to $100 a day from the date of such failure or refusal and the court may in its discretion order such other relief as it deems proper. Section 103(c) of PFEA '04 provides that the Secretary of Labor shall, not later than 1 year after the date of the enactment of PFEA '04, issue regulations (including a model notice) necessary to implement the amendments made by section 103. Section 103(d) of PFEA '04 provides that the amendments made by section 103 of PFEA '04 shall apply to plan years beginning after December 31, 2004.

B. Overview of Proposed Regulation

Paragraph (a) of the proposed regulation implements the requirements set forth in section 101(f)(1) of the Act. This section in general requires the administrator of a multiemployer defined benefit pension plan to furnish annually a notice of the plan's funded status to the plan's participants and beneficiaries and other specified interested parties (each labor organization representing such participants or beneficiaries, each employer that has an obligation to contribute under the plan, and the Pension Benefit Guaranty Corporation (PBGC)). Those persons entitled to the notice are further clarified in paragraph (f) of the proposed regulation.

Paragraph (a)(2) provides a limited exception to the requirement to furnish the annual funding notice. Under the exception, the plan administrator of a plan receiving financial assistance from the PBGC is not required to furnish the annual funding notice to the parties otherwise entitled to such notice. The Department, after consulting with the PBGC, is of the view that such notice would be of little, if any, value to such parties in light of the PBGC's authority and responsibility under title IV of ERISA with respect to insolvent multiemployer plans.[1]

Paragraph (b) of the proposed regulation sets forth the content requirements of the notice required under section 101(f). Paragraph (b) requires that the identification and financial information included in the notice is consistent with the information included in the plan's Annual Return/Report filed for the plan year to which the notice relates.

Specifically, paragraph (b)(1)–(4) provides that the notice shall include: The name of the plan; the address and phone number of the plan administrator and the plan's principal administrative officer (if different from the plan administrator); the plan sponsor's employer identification number (currently line 2(b) of the Annual Return/Report Form 5500); and the plan number (currently line 1(b) of the Annual Return/Report Form 5500).

Paragraph (b)(5)–(8) further provides that the notice shall include information relevant to the plan's funding, including: a statement as to whether the plan's funded current liability percentage (calculated by dividing the actuarial value of the plan's assets (currently line 1b(2) of the Schedule B of the Annual Return/Report Form 5500) by the current liability (currently line 2b(4), column (3), of the Schedule B of the Annual Return/Report Form 5500) for the plan year to which the notice relates is at least 100 percent (and, if not, the actual percentage); a statement of the market value of the plan's assets (currently line 1b(1) of the Schedule B of the Annual Return/Report Form 5500) and the valuation date, the

[1] The provisions of title IV of ERISA that apply in the context of a plan's receipt of financial assistance from the PBGC (sections 4245(e) and 4281(d)) ensure that participants and beneficiaries of insolvent plans are adequately informed of, among other things, their plan's funding status (including for participants in pay status, their individual benefit levels), and PBGC's benefit guarantees. In addition, PBGC receives plan financial information before providing financial assistance. Inasmuch as the foregoing title IV provisions are largely duplicative of the requirements in section 101(f) of ERISA, an exception from the requirements of section 101(f) for plans receiving financial assistance necessarily would reduce administrative costs to these plans, thereby increasing the plan's available resources for benefit payments.

amount of benefit payments for the plan year to which the notice relates (currently line 2e(4) of the Schedule H of the Annual Return/Report Form 5500), and the ratio of the assets to the benefit payments for the plan year to which the notice relates; a summary of the rules governing insolvent multiemployer plans, including the limitations on benefit payments and any potential benefit reductions and suspensions (and the potential effects of such limitations, reductions, and suspensions on the plan); and a general description of the benefits under the plan that are eligible to be guaranteed by the PBGC, along with an explanation of the limitations on the guarantee and the circumstances under which such limitations apply.

Paragraph (b)(9) of the proposed regulation permits inclusion in the notice of any additional information that the administrator determines would be helpful to understanding the information required to be contained in the notice.

Paragraphs (c) and (e) of the proposed regulation, respectively, set forth the form and manner requirements relating to the notice. Paragraph (c) of the proposed regulation provides that notices shall be written in a manner calculated to be understood by the average plan participant. *See* 29 CFR 2520.102–2. Paragraph (e) of the proposed regulation provides that notices (except for notices to the PBGC) shall be furnished in a manner consistent with the requirements of 29 CFR 2520.104b–1. Collectively, these requirements are intended to ensure that notices are written so that the average plan participant can understand them, and that they are provided in a form reasonably accessible to those individuals eligible to receive the notice. In addition, the Department believes that plan administrators already are familiar with the rules in §§ 2520.102–2 and 2520.104b–1, thereby easing the burden of compliance with this regulation.

The Department worked with the PBGC to develop model language for use in connection with funding notices. Such language is set forth in a model notice in the appendix to the regulation. Use of the model notice is not mandatory. However, paragraph (g) of the proposed regulation provides that, by using the model notice, the plan administrator will be deemed to satisfy its duties with respect to the requirements of paragraphs (b) and (c) of the proposed regulation, except with respect to information referenced in paragraph (b)(9) of the regulation.

Paragraph (d) provides that notices shall be furnished within 9 months after the close of the plan year, unless the Internal Revenue Service has granted an extension of time to file the annual report, in which case the notice shall be furnished within 2 months after the close of the extension period. This paragraph implements the requirements of section 101(f)(3) of the Act, which provides that annual funding notices shall be provided to recipients no later than two months after the deadline (including extensions) for filing the annual report for the plan year to which the notice relates.

Paragraph (f) of the proposed regulation delineates the persons to whom funding notices required by this section must be furnished. In an effort to limit administrative burdens and costs attendant to compliance with this notice requirement, paragraph (f) of the proposal limits an administrator's disclosure obligation to only individuals who are participants on the last day of the plan year to which the notice relates, beneficiaries receiving benefits under the plan on the last day of the plan year to which the notice relates, labor organizations representing participants under the plan on the last day of the plan year to which the notice relates, and each employer that, as of the last day of the plan year to which the notice relates, is a party to the collective bargaining agreement(s) pursuant to which the plan is maintained or who otherwise may be subject to withdrawal liability. By focusing on a person's status on the last day of the previous plan year, the plan administrator is thereby relieved of additional costs of tracking and providing notice to individuals, labor organizations and employers who may no longer have an interest in the plan's funding condition.

Paragraph (f)(4) provides a more detailed clarification of which employers are entitled to an annual funding notice. Specifically, the language ''is a party to the collective bargaining agreement(s) pursuant to which the plan is maintained'' therein is intended to cover not only employers that have a present obligation to contribute under the plan, but also those whose obligation may be temporarily suspended due to a funding holiday granted by the plan's board of trustees. In addition, the Department, through its use of the phrase ''or who otherwise may be subject to withdrawal liability,'' intends to make it clear that, in the case of plans that cover employees in the building and construction industry, entertainment industry, or trucking, household goods moving and public warehousing industries, notice is required for any employer that, as of the last day of the plan year to which the notice relates, has ceased to have an obligation to contribute under the plan, but has continued exposure to withdrawal liability pursuant to section 4203(b), (c), or (d) of ERISA. The clarification in paragraph (f)(4) is intended to ensure that all employers that have a direct financial interest in the plan's funding status will receive a notice.

C. Request for Comments

The Department invites comments from interested persons on all aspects of the proposed regulation. Comments should be addressed to the Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5669, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attn: PFEA '04 Project. Comments also may be submitted electronically to *e-ORI@dol.gov.* All comments received will be available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue NW., Washington, DC 20210.

The Department has limited the comment period to 30 days in order to issue a final regulation on the earliest possible date, taking into account Congress' expectation that regulations would be issued not later than one year from enactment of the PFEA '04, which was April 10, 2004. The Department believes that, in light of the limited number of issues presented for consideration by the proposal, the provided 30-day comment period affords interested persons an adequate amount of time to analyze the proposal and submit comments.

D. Regulatory Impact Analysis

Summary

This proposed regulation contains a model notice and other guidance necessary to implement the amendments made by new section 101(f) of ERISA, as enacted by section 103(a) of PFEA '04. The regulation, if adopted as proposed, will offer a model notice to administrators of multiemployer defined benefit plans, which is expected to mitigate burden and contribute to the efficiency of compliance.

The multiemployer defined benefit plan funding notice provision of PFEA '04 was enacted amid concerns about persisting low interest rates and declines in equity values, each of which has an increasing effect on contribution

requirements and a decreasing effect on the funding levels of defined benefit plans. More complete and timelier disclosures were considered an important element of measures enacted in PFEA '04 to strengthen the long-term health of the defined benefit pension system. Increasing the transparency of information about the funding status of multiemployer plans for participants and beneficiaries, the labor organizations representing them, contributing employers, and PBGC will afford all parties interested in the financial viability of these plans greater opportunity to monitor their funding status.

According to a March 2004 Report by the General Accounting Office [2] the regulatory framework within which multiemployer plans operate shifts certain financial risks away from the government and by implication the taxpayer. Contributing employers to multiemployer plans share the risk of funding benefits for all participants, not just those in their employment, and face specific liabilities if they withdraw from the plans. Participants in multiemployer plans face lower benefit guaranties than those in single-employer plans. According to the GAO report, these factors create incentives for participants and employers to work together constructively to find solutions to plans' financial difficulties. These notices will provide timely disclosure of information concerning the funding status of these plans to support the effort of all interested parties to monitor their financial condition and take action where necessary.

The regulation would further afford plan administrators greater certainty that they have discharged their notice obligation under section 101(f). The proposed regulation is also intended to clarify certain terms used in section 101(f) for the general purpose of delineating those persons entitled to receive the notice. The benefits of greater efficiency, certainty, and clarity are expected to be substantial, but cannot be specifically quantified.

The cost of the multiemployer defined benefit plan notices is expected to amount to $777,000 in the year of implementation, and $644,000 in each subsequent year. The total estimated cost includes the one-time development of a notice by each plan, and the annual preparation and mailing by the administrators of all multiemployer defined benefit plans of the required notices to plan participants and beneficiaries, specified labor organizations, employers that have an obligation to contribute to these plans, and to the Pension Benefit Guaranty Corporation. The first year estimate is higher to account for the time required for plan administrators to adapt and review the model notice.

In this proposed regulation, the Department has attempted to provide guidance to assist administrators to meet this objective the most economically efficient way possible. Because the costs of this proposal arise from notice provisions in PFEA '04, the data and methodology used in developing these estimates are more fully described in the Paperwork Reduction Act section of this analysis of regulatory impact.

Executive Order 12866

Under Executive Order 12866 (58 FR 51735), the Department must determine whether a regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined that this proposed regulation is significant within the meaning of section 3(f)(4) of the Executive Order. OMB has, therefore, reviewed this proposed regulation pursuant to the Executive Order.

Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department of Labor conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, EBSA is soliciting comments concerning the proposed information collection request (ICR) included in the proposed regulation regarding the Annual Funding Notice for Defined Benefit Multiemployer Pension Plans. A copy of the ICR may be obtained by contacting the PRA addressee shown below.

The Department has submitted a copy of the proposed information collection to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Department and OMB are particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Attention: Desk Officer for the Employee Benefits Security Administration. Although comments may be submitted through April 5, 2005, OMB requests that comments be received within 30 days of publication of the Notice of Proposed Rulemaking to ensure their consideration.

PRA Addressee: Address requests for copies of the ICR to Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Room N–5647, Washington, DC 20210.

[2] See GAO–04–423 Private Pensions. Multiemployer Plans Face Short and Long-Term Challenges. U.S. General Accounting Office, March 2004. General Accounting Office name changed to Government Accountability Office effective July 7, 2004.

Telephone (202) 693–8410; Fax: (202) 219–5333. These are not toll-free numbers.

The information collection provisions of this proposed regulation are found in § 2520.101–4. A model notice is provided in the Appendix to §2520.101–4 to facilitate compliance and moderate the burden attendant to supplying notices to participants and beneficiaries, labor organizations, contributing employers, and PBGC as required by PFEA '04 and the proposed regulation. Use of the model notice is not mandatory; however, use of the model will be deemed to satisfy the requirements for content, style, and format of the notice, except with respect to any other information the plan administrator elects to include. This proposed regulation is also intended to clarify certain of the PFEA '04 requirements as to content, style and format, manner of furnishing, and persons entitled to receive notice.

In order to estimate the potential costs of the notice provisions of section 101(f) of ERISA and this proposed regulation, the Department estimated the number of multiemployer defined benefit plans, and the numbers of participants, beneficiaries receiving benefits, labor organizations representing participants, and employers that have an obligation to contribute to these plans. The PBGC Pension Insurance Data Book 2003 indicates that as of September 30, 2003, there were 1,623 multiemployer defined benefit plans with 9.7 million participants and beneficiaries receiving benefits. These estimates are based on premium filings with PBGC for 2002, projected by PBGC to 2003, generally the most recent information currently available. This total has been adjusted to 1,595 to reflect the exception from the requirement to furnish a funding notice for years in which a plan is receiving financial assistance from PBGC.

The Department is not aware of a direct source of information as to the number of labor organizations that represent participants of multiemployer defined benefit plans and that would be entitled to receive notice under section 101(f). As a proxy for this number, the Department has relied on information supplied by the Department's Employment Standards Administration, Office of Labor Management Standards, as to the number of labor organizations that filed required annual reports for their most recent fiscal year, generally 2002, at this time. The Department adjusted the number provided by excluding labor organizations that appeared to represent only state, local, and federal governmental employees to account for the fact that such employees are generally unlikely to be participants in plans covered under Title I of ERISA. The resulting estimate of labor organizations entitled to receive notice is 21,000. Although this number has been used for purposes of this analysis, it is believed that this number is an upper bound for the actual number of labor organizations that will receive notice because it is likely that some labor organizations do not represent participants in defined benefit plans, or that some labor organizations represent only participants in single employer plans not subject to section 101(f).

The Department is also unaware of a source of information for the current number of employers obligated to contribute to multiemployer defined benefit plans. PBGC assisted with development of an estimate of this number by providing the Department with a tabulation on their 1987 premium filings of the number of employers contributing to multiemployer defined benefit plans at that time. This was the last year this data element was required to be reported. The Department has attempted to validate that 1987 figure by dividing the number of participants in multiemployer defined benefit plans in the industries in which these plans are most concentrated, such as construction, trucking, and retail food sales,[3] by the average number of employees per firm in those industries based on data published by the Office of Advocacy, U.S. Small Business Administration for 2001. This computation resulted in a figure that was similar in magnitude, but somewhat higher than the 277,600 employers reported in the PBGC premium filing data. As a result, the Department has used 300,000 for its estimate of the number of contributing employers to whom the required notice will be sent.

For purposes of its estimates of regulatory impact, then, the Department has assumed that each plan will develop a notice, and that each year the multiemployer defined benefit plan notices will be prepared and sent by the administrators of 1,595 plans to 9.7 million participants and beneficiaries, 21,000 labor organizations, and 300,000 contributing employers, and to PBGC, for a total of about 10 million notices.

It is assumed that the availability of a model notice as provided in paragraph (f) will lessen the time otherwise required by a plan administrator to draft a required notice. In developing burden estimates, the Department has included one hour for reviewing and adapting the model notice, and 30 minutes for completing the notice for each plan. Reviewing and adapting the notice is expected to be performed by service providers, specifically by legal counsel at an hourly rate of $83. This accounts for the estimated burden of developing the notice, which amounts to about $133,000 for the 1,595 plans. Completing the notice by adding information relevant to each year is expected to take 30 minutes in the first year of implementation, as well as in subsequent years, and it is expected to be performed by the same professionals who are accounted for as preparing the Summary Annual Report (SAR) for plans, namely financial professionals at the rate of $68 per hour. The assumed preparation cost to plans to complete the notice is therefore about $55,000 per year. The total cost to plans to develop and complete the notice in the year of implementation is about $187,000.

The estimated distribution costs for the notices are based on separate assumptions for participant and beneficiary notices versus the labor organization, contributing employer, and PBGC notices. The distribution cost for the notices to participants and beneficiaries is relatively modest compared to the number of notices because it is assumed that these notices will be provided at the same time and as part of the same mailing as the Summary Annual Report. The mailing costs for the SAR are already accounted for in the ICR for the SAR, currently approved under OMB Control Number 1210–0040. Therefore, only an additional materials cost is accounted for in the estimate of distribution costs for participant and beneficiary notices, which totals $292,000.

Distribution cost estimates for the notices to labor organizations, employers, and PBGC include $0.40 for materials and postage, and two minutes at a clerical wage rate of about $17 for each notice. Total distribution costs to labor organizations, contributing employers, and PBGC, therefore, are expected to total about $316,000. Distribution costs for all notices are estimated at $608,000.

In order to estimate the hour burden of preparation and distribution of the notices, the Department has generally relied on the same assumptions used for estimates of the burden of SAR preparation and distribution. Specifically, it is assumed that 100% of notices are developed by service providers, and that 90% of notices are prepared and distributed by service providers. Those activities are

[3] Multiemployer Plans Face Short and Long-Term Challenges. U.S. General Accounting Office, March 2004. General Accounting Office name changed to Government Accountability Office effective July 7, 2004. See GAO–04–423 Private Pensions.

appropriately accounted for as cost burden, for which plans pay service providers. The remaining 10% of notices prepared and distributed in house by plan administrators are appropriately accounted for as hour burden. Materials and mailing costs are considered direct cost burden, as well. The Department has not accounted here for reductions in mailing and material costs that might arise from the electronic distribution of some notices. Although such distribution may be deemed to satisfy the requirements of section 2520.104b–1(b)(1) with respect to fulfilling the disclosure obligation if conditions of section 2520.104b–1(c) are satisfied, it is assumed for purposes of these estimates that these funding notices are less likely to be provided electronically due to the nature of the industries involved and the relationships of the parties affected by this requirement since the active workers affected often do not have access to e-mail at their workplaces. The resulting hour and cost burden estimates are shown below. The Department requests comments on the data, assumptions, and methodology used in arriving at these estimates of economic impact and PRA 95 burden.

Type of Review: New.

Agency: Department of Labor, Employee Benefits Security Association.

Title: Multiemployer Defined Benefit Plan Funding Notice.

OMB Number: 1210-NEW.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Respondents: 1,595.

Frequency of Response: Annual.

Responses: 10,048,000.

Estimated Total Burden Hours: 1,155.

Total Annualized Capital/Startup Costs: $133,000.

Total Annual Cost (Operating and Maintenance): $644,000.

Total Annualized Cost: $777,000.

OMB will consider comments submitted in response to this request in its review of the request for approval of the ICR; these comments will also become a matter of public record.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and which are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a proposed rule is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires that the agency present an initial regulatory flexibility analysis at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities and seeking public comment on such impact. Small entities include small businesses, organizations and governmental jurisdictions.

For purposes of analysis under the RFA, the Employee Benefits Security Administration (EBSA) proposes to continue to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants. Under section 104(a)(3), the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of section 104(a)(3), the Department has previously issued at 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46 and 2520.104b–10 certain simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans covering fewer than 100 participants and which satisfy certain other requirements.

Further, while some large employers may have small plans, in general small employers maintain most small plans. Thus, EBSA believes that assessing the impact of this proposed rule on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*). EBSA therefore requests comments on the appropriateness of the size standard used in evaluating the impact of this proposed rule on small entities. The Department does not expect that the plans potentially impacted by this proposal will be small entities. However, the Department requests comments on the potential impact of proposal on small entities, and on ways in which any burdens on small entities might be minimized.

EBSA has preliminarily determined that this rule will not have a significant economic impact on a substantial number of small entities. In support of this determination, EBSA has prepared the following initial regulatory flexibility analysis.

Section 103(c) of PFEA '04 provides that the Secretary of Labor shall issue regulations (including a model notice) necessary to implement the amendments made by new section 101(f) of ERISA, as enacted by section 103(a) of PFEA '04. Section 101(f) of ERISA requires the administrator of a multiemployer defined benefit pension plan to furnish annually a notice of the plan's funded status to the plan's participants and beneficiaries and other specified interested parties (each labor organization representing such participants and beneficiaries, each employer that has an obligation to contribute under the plan, and the PBGC).

The conditions set forth in this proposed regulation are intended to satisfy the PFEA '04 requirement that the Secretary prescribe regulations (including a model notice) necessary to implement the amendments made by section 103.

The proposed rule would impact small plans that are multiemployer defined benefit pension plans. It is expected that the proposal will affect approximately 10 small plans, and 800 participants in small plans.

The initial cost of the funding notice for small plans is expected to be about $82 per plan. Preparation of this information is in most cases accomplished by professionals that provide services to employee benefit plans.

The benefits of greater certainty afforded fiduciaries by the model notice are substantial but cannot be specifically quantified.

To the Department's knowledge, there are no federal regulations that might duplicate, overlap, or conflict with the proposed regulation for multiemployer defined benefit pension plan funding notices under section 101(f) of ERISA.

Congressional Review Act

The rules being issued here are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and if finalized will be sent to Congress and the Comptroller General for review. The rule is not a ''major rule'' as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects

on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, this proposed regulation does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, and does not impose an annual burden exceeding $100 million on the private sector.

Federalism Statement

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This final rule does not have federalism implications because it has no 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. Section 514 of ERISA provides, with certain exceptions specifically enumerated that are not pertinent here, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The requirements implemented in this final rule do not alter the fundamental reporting and disclosure requirements of the statute with respect to employee benefit plans, and as such have no implications for the States or the relationship or distribution of power between the national government and the States.

List of Subjects in 29 CFR Part 2520

Accounting, Employee benefit plans, Pensions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Labor proposes to amend 29 CFR part 2520 as follows:

PART 2520—RULES AND REGULATIONS FOR REPORTING AND DISCLOSURE

1. The authority citation for part 2520 is revised to read as follows:

Authority: 29 U.S.C. 1021–1025, 1027, 1029–31, 1059, 1134 and 1135; and Secretary of Labor's Order 1–2003, 68 FR 5374 (Feb. 3, 2003). Sec. 2520.101–2 also issued under 29 U.S.C. 1132, 1181–1183, 1181 note, 1185, 1185a–b, 1191, and 1191a–c. Secs. 2520.102–3, 2520.104b–1 and 2520.104b–3 also issued under 29 U.S.C. 1003,1181–1183, 1181 note, 1185, 1185a–b, 1191, and 1191a–c. Secs. 2520.104b–1 and 2520.107 also issued under 26 U.S.C. 401 note, 111 Stat. 788. Section 2520.101–4 also issued under sec. 103 of Pub. L. 108–218.

2. Add the following new section and related appendix to subpart A:

§ 2520.101–4 Annual funding notice for multiemployer defined benefit pension plans.

(a) *In general.* (1) Except as provided in paragraph (a)(2) of this section, pursuant to section 101(f) of the Act, the administrator of a defined benefit, multiemployer pension plan shall furnish annually to each person specified in paragraph (f) of this section a funding notice that conforms to the requirements of this section.

(2) A plan administrator shall not be required to furnish a funding notice for any plan year for which the plan is receiving financial assistance from the Pension Benefit Guaranty Corporation pursuant to section 4261 of ERISA.

(b) *Content of notice.* A funding notice shall, consistent with the information included in the plan's Annual Return/Report Form 5500 filed for the plan year to which the funding notice relates, include the following information:

(1) The name of the plan;

(2) The address and phone number of the plan administrator and the plan's principal administrative officer (if different from the plan administrator);

(3) The plan sponsor's employer identification number;

(4) The plan number;

(5) A statement as to whether the plan's funded current liability percentage (as defined in section 302(d)(8)(B)) for the plan year to which the notice relates is at least 100 percent (and, if not, the actual percentage);

(6) A statement of the market value of the plan's assets (and valuation date), the amount of benefit payments, and the ratio of the assets to the payments for the plan year to which the notice relates;

(7) A summary of the rules governing insolvent multiemployer plans, including the limitations on benefit payments and any potential benefit reductions and suspensions (and the potential effects of such limitations, reductions, and suspensions on the plan);

(8) A general description of the benefits under the plan which are eligible to be guaranteed by the Pension Benefit Guaranty Corporation, along with an explanation of the limitations on the guarantee and the circumstances under which such limitations apply; and

(9) Any additional information that the plan administrator elects to include, provided that such information is necessary or helpful to understanding the mandatory information in the notice.

(c) *Style and format of notice.* Funding notices shall be written in a manner calculated to be understood by the average plan participant.

(d) *When to furnish notice.* A funding notice shall be furnished within 9 months after the close of the plan year, unless the Internal Revenue Service has granted an extension of time to file the annual report, in which case such furnishing shall take place within 2 months after the close of the extension period.

(e) *Manner of furnishing notice.* (1) Except as provided in paragraph (e)(2) of this section, funding notices shall be furnished in any manner consistent with the requirements of § 2520.104b–1 of this chapter, including paragraph (c) of that section relating to the use of electronic media.

(2) Notice shall be furnished to the Pension Benefit Guaranty Corporation in a manner consistent with the requirements of part 4000 of this title.

(f) *Persons entitled to notice.* Persons entitled to notice under this section include:

(1) Each participant covered under the plan on the last day of the plan year to which the notice relates;

(2) Each beneficiary receiving benefits under the plan on the last day of the plan year to which the notice relates;

(3) Each labor organization representing participants under the plan on the last day of the plan year to which the notice relates;

(4) Each employer that, as of the last day of the plan year to which the notice relates, is a party to the collective bargaining agreement(s) pursuant to which the plan is maintained or who otherwise may be subject to withdrawal liability pursuant to section 4203 of the Act; and

(5) The Pension Benefit Guaranty Corporation.

(g) *Model notice.* The appendix to this section contains a model notice that is intended to assist plan administrators in

discharging their notice obligations under this section. Use of the model notice is not mandatory. However, use of the model notice will be deemed to satisfy the requirements of paragraphs (b) and (c) of this section, except with respect to information referenced in paragraph (b)(9) of this section.

Appendix to § 2520.101–4—Annual Funding Notice for [Insert name of pension plan]

Introduction

This notice, which federal law requires all multiemployer plans to send annually, includes important information about the funding level of [insert name, number, and EIN of plan] (Plan). This notice also includes information about rules governing insolvent plans and benefit payments guaranteed by the Pension Benefit Guaranty Corporation (PBGC), a federal agency. This notice is for the plan year beginning [insert beginning date] and ending [insert ending date] (Plan Year).

Plan's Funding Level

The Plan's ''funded current liability percentage'' for the Plan Year was [insert percentage—see instructions below]. In general, the higher the percentage, the better funded the plan. The funded current liability percentage, however, is not indicative of how well a plan will be funded in the future or if it terminates.

(Instructions: For purposes of computing the ''funded current liability percentage,'' insert ratio of actuarial value of assets to current liability, expressed as a percentage. If the percentage is equal to or greater than 100 percent, you may insert ''at least 100 percent.'')

Plan's Financial Information

The market value of the Plan's assets as of [insert valuation date] was [insert amount]. The total amount of benefit payments for the Plan Year was [enter amount]. The ratio of assets to benefit payments is [enter amount calculated by dividing the value of plan assets by the total benefit payments]. This ratio suggests that the Plan's assets could provide for approximately [enter amount calculated above] years of benefit payments in annual amounts equal to what was paid out in the Plan Year. However, the ratio does not take into account future changes in total benefit payments or plan assets.

Rules Governing Insolvent Plans

The law has special rules governing insolvent multiemployer pension plans. A plan is insolvent for a plan year if its available financial resources are not sufficient to pay benefits when due for the plan year.

An insolvent plan must reduce benefit payments to the highest level that can be paid from the plan's available financial resources. If such resources are not enough to pay benefits at a level specified by law (see Benefit Payments Guaranteed by the PBGC, below), the plan must apply to the PBGC for financial assistance. The PBGC, by law, will loan the plan the amount necessary to pay benefits at the guaranteed level. Reduced benefits may be restored if the plan's financial condition improves.

A plan that becomes insolvent must provide prompt notification of the insolvency to participants and beneficiaries, contributing employers, labor unions representing participants, and PBGC. In addition, participants and beneficiaries also must receive information regarding whether, and how, their benefits will be reduced or affected as a result of the insolvency, including loss of a lump sum option. This information will be provided for each year the plan is insolvent.

Benefit Payments Guaranteed by the PBGC

The PBGC guarantees only vested benefits. Specifically, it guarantees a monthly benefit payment equal to 100 percent of the first $11 of the Plan's monthly benefit accrual rate, plus 75 percent of the next $33 of the accrual rate, times each year of credited service. The maximum guaranteed payment for a vested retiree, therefore, is $35.75 per month times each year of credited service.

Example 1: If a participant with 10 years of credited service has an accrued monthly benefit of $500, the accrual rate for purposes of determining the PBGC guarantee would be determined by dividing the monthly benefit by the participant's years of service ($500/10), which equals $50. The guaranteed amount for a $50 monthly accrual rate is equal to the sum of $11 plus $24.75 (.75 × $33), or $35.75. Thus, the participant's guaranteed monthly benefit is $357.50 ($35.75 × 10).

Example 2: If the participant in Example 1 has an accrued monthly benefit of $200, the accrual rate for purposes of determining the guarantee would be $20 (or $200/10). The guaranteed amount for a $20 monthly accrual rate is equal to the sum of $11 plus $6.75 (.75 × $9), or $17.75. Thus, the participant's guaranteed monthly benefit would be $177.50 ($17.75 × 10).

In calculating a person's monthly payment, the PBGC will disregard any benefit increases that were made under the plan within 60 months before insolvency. Similarly, the PBGC does not guarantee pre-retirement death benefits to a spouse or beneficiary (*e.g.*, a qualified pre-retirement survivor annuity), benefits above the normal retirement benefit, disability benefits not in pay status, or non-pension benefits, such as health insurance, life insurance, death benefits, vacation pay, or severance pay.

Where To Get More Information

For more information about this notice, you may contact [enter name of plan administrator and, if applicable, principal administrative officer], at [enter phone number and address]. For more information about the PBGC and multiemployer benefit guarantees, go to PBGC's Web site, *http://www.pbgc.gov*, or call PBGC toll-free at 1–800–400–7242 (TTY/TDD users may call the Federal relay service toll free at 1–800–877–8339 and ask to be connected to 1–800–400–7242).

Signed at Washington, DC, this 31st day of January, 2005.

Ann L. Combs,

Assistant Secretary, , Employee Benefits Security Administration, Department of Labor.

[FR Doc. 05–2151 Filed 2–3–05; 8:45 am]

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A cumulative List of Public Laws for the second session of the 108th Congress will appear in the issue of January 31, 2005.

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