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WHEN: Tuesday, July 8, 2008
9:00 a.m.–Noon

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

RESERVATIONS: (202) 741–6008

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

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Parts 402 and 407

RIN 0563–AC17

Catastrophic Risk Protection Endorsement and the Group Risk Plan of Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) amends the Catastrophic Risk Protection Endorsement (7 CFR 402.4) (CAT Endorsement), and the Group Risk Plan Common Policy (7 CFR 407.9) (GRP policy) to incorporate changes in the administrative fees for catastrophic risk protection mandated by the Food, Conservation, and Energy Act of 2008 (Farm Bill 2008).

DATES: *Effective Date:* This rule is effective June 25, 2008.

FOR FURTHER INFORMATION CONTACT: Erin Albright, Risk Management Specialist, Product Management, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility—Mail Stop 0812, PO Box 419205, Kansas City, MO 64141–6205, telephone (816) 926–7730.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

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

Paperwork Reduction Act of 1995

Pursuant to the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collections of information in this rule have been approved by OMB under control number 0563–0053 through June 30, 2008.

E-Government Act Compliance

FCIC is committed to complying with the E-Government Act of 2002, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Executive Order 13132

It has been determined under section 1(a) of Executive Order 13132, Federalism, that this rule does not have sufficient implications to warrant consultation with the States. The provisions contained in this rule will not have a substantial direct effect on States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

FCIC certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Administrative fee requirements for the Federal crop insurance program are the same for all producers regardless of the size of their operations. Whether a producer has 10 acres or 100 acres there is no difference in the administrative fee requirements. To ensure crop insurance is available to small entities, the Federal Crop Insurance Act authorizes FCIC to waive collection of administrative fees from limited resource farmers. FCIC believes this change helps ensure that small entities are given the same opportunities as large entities to manage their risks through the use of crop insurance. A Regulatory Flexibility Analysis has not been prepared since this regulation does not have an impact on small entities, and, therefore, this regulation is exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605).

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. With respect to any direct action taken by FCIC or to require the insurance provider to take specific action under the terms of the crop insurance policy, the administrative appeal provisions published at 7 CFR part 11 must be exhausted before any action against FCIC for judicial review may be brought.

Environmental Evaluation

This action is not expected to have a significant economic impact on the quality of the human environment, health, or safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Background

On May 22, 2008, the 2008 Farm Bill was enacted. Section 12006 of the 2008 Farm Bill requires that each producer pay an administrative fee for catastrophic risk protection (CAT) in the amount of $300 per crop per county. The provisions are very specific and mandate certain terms that do not allow FCIC any discretion in the provisions or their implementation. Currently, the administrative fee for catastrophic risk protection is $100 per crop per county. Further, that section expressly

authorizes cooperative and trade associations to pay the administrative fee for CAT coverage under certain circumstances. Provisions have been modified to allow such associations to pay the CAT administrative fee.

To effectuate this mandated change, FCIC is revising the CAT Endorsement and the GRP policy.

Good cause is shown to make this rule effective upon filing for public inspection at the Office of the **Federal Register**. Good cause exists when notice and comment and the 30 day delay in the effective date is impracticable, unnecessary, or contrary to the public interest.

FCIC is merely making ministerial changes to the policy that are mandated by the 2008 Farm Bill. There is no discretion given to FCIC in the terms contained in this rule or their implementation. Further, the next applicable contract change date, the date by which changes to the policy must be made to have them effective for the next crop year, is June 30, 2008. Therefore, there is no time to conduct a notice and comment rulemaking.

For the reasons stated above, good cause exists to make these policy changes effective upon filing for public inspection at the Office of the Federal Register.

List of Subjects in 7 CFR Parts 402 and 407

Crop insurance, Reporting and recordkeeping requirements.

Final Rule

■ Accordingly, as set forth in the preamble, the Federal Crop Insurance Corporation amends 7 CFR parts 402 and 407 effective for the 2009 and succeeding crop years for all crops with a 2009 crop year contract change date on or after the effective date of this rule, and for the 2010 and succeeding crop years for all crops with a 2009 crop year contract change date prior to the effective date of this rule, as follows:

PART 402—CATASTROPHIC RISK PROTECTION ENDORSEMENT

■ 1. The authority citation for 7 CFR Part 402 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

■ 2. Amend § 402.4:

■ a. By removing the introductory text; and

■ b. In section 6, by revising the introductory text of paragraph (b) and paragraph (b)(1) to read as follows:

§ 402.4 Catastrophic Risk Protection Endorsement Provisions.

* * * * *

6. Annual Premium and Administrative Fees.

* * * * *

(b) In return for catastrophic risk protection coverage, you must pay an administrative fee to us within 30 days after you have been billed, unless otherwise authorized in the Federal Crop Insurance Act (You will be billed by the date stated in the Special Provisions);

(1) The administrative fee owed is $300 for each crop in the county unless otherwise specified in the Special Provisions.

* * * * *

PART 407—GROUP RISK PLAN OF INSURANCE REGULATIONS

■ 1. The authority citation for 7 CFR Part 407 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

■ 2. Revise the part heading as set forth above.

■ 3. Amend § 407.9:

■ a. By removing the introductory text; and

■ b. In section 8 by revising the introductory text of paragraph (a) and paragraph (a)(1) to read as follows:

§ 407.9 Group risk plan common policy.

* * * * *

8. Administrative Fees and Annual Premium.

(a) If you obtain a catastrophic risk protection GRP policy, you will pay an administrative fee, unless otherwise authorized in the Act:

(1) Of $300 per crop per county unless otherwise specified in the Special Provisions;

* * * * *

Signed in Washington, DC, on June 24, 2008.

Eldon Gould,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 08–1395 Filed 6–25–08; 11:42 am]

BILLING CODE 3410–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0163; Airspace Docket No. 08–AGL–2]

Amendment of Class E Airspace; Indianapolis, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This action confirms the effective date of a direct final rule that establishes additional Class E airspace at Indianapolis, IN, published in the **Federal Register** April 2, 2008 (73 FR 17887) Docket No. FAA–2008–0163. This action also makes a minor correction to the geographic coordinates of Hendricks County Gordon Graham Field.

DATES: *Effective Date:* 0901 UTC June 27, 2008. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Gary Mallett, NISC Contractor, Operations Support Group, ATO Central Service Center, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd, Fort Worth, TX 76193–0530; at telephone (817) 222–4949.

SUPPLEMENTARY INFORMATION:

History

The FAA published a direct final rule with request for comments in the **Federal Register** April 2, 2008, (73 FR 17887), Docket No. FAA–2008–0163, that establishes additional Class E airspace at Indianapolis, IN. The FAA uses the direct final rule procedure for non-controversial rules where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit an adverse comment, was received within the comment period, the regulation would become effective on June 5, 2008. No adverse comments were received; thus, this notice confirms that the direct final rule will become effective on this date. Also an error was found in the geographic coordinates of Hendricks County Gordon Graham Field. This action corrects that error.

The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9R, Airspace Designations and Reporting Points, signed August 15, 2007, and effective September 15, 2007, is hereby amended as follows:

Correction

In the **Federal Register** dated April 2, 2008, (73 FR 14887), **Federal Register** Docket No. FAA–2008–0163, on page 17888, column 2, line 47, replace the coordinates for Hendricks County-

Gordon Graham Field as follows: (Lat. 39°44′48″ N, Long. 86°28′31″ W).

* * * * *

Issued in Fort Worth, TX on June 17, 2008.

Donald R. Smith,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. E8–14381 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–0309; Airspace Docket No. 07–AEA–20]

Amendment of Class E Airspace; Gettysburg, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule, confirmation of effective date.

SUMMARY: This action confirms the effective date of a direct final rule published in the **Federal Register** (73 FR 8593) that modifies Class E Airspace at Gettysburg, PA. Additional controlled airspace at Gettysburg Regional Airport will now provide the controlled airspace required to support the new Copter Area Navigation (RNAV) Global Positioning System (GPS) 070 Point in Space (PinS) approach developed to facilitate helicopter medical flight arrivals and departures at Gettysburg Hospital, Gettysburg, PA.

DATES: Effective 0901 UTC June 27, 2008. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Melinda Giddens, System Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; Telephone (404) 305–5610; Fax (404) 305–5572.

SUPPLEMENTARY INFORMATION:

Confirmation of Effective Date

The FAA published this direct final rule with a request for comments in the **Federal Register** on February 14, 2008 (73 FR 8593), Docket No. FAA 2007–0309; Airspace Docket No. 07–AEA–20. The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on June 5, 2009. No adverse comments were received, and this notice confirms that effective date.

Issued in College Park, Georgia, on May 19, 2008.

Barry A. Knight,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. E8–14384 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0131; Airspace Docket 08–AEA–12]

Establishment of Class E Airspace; Philippi, WV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Philippi, WV, to accommodate a new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAP) Runways (RWY) 08–26 that has been developed for Philippi/Barbour County Regional Airport. As a result, controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to contain the SIAP and for Instrument Flight Rule (IFR) operations at Philippi/Barbour County Regional Airport. The operating status of the airport will change from Visual Flight Rules (VFR) to include IFR operations concurrent with the publication of the SIAP.

DATES: Effective Date: 0901 UTC, September 25, 2008. The Director of the Federal Register approves this incorporation by reference action under title 1 Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

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

SUPPLEMENTARY INFORMATION:

History

On March 18, 2008, the FAA proposed to amend Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace at Philippi, WV (73 FR 14408). This action provides adequate Class E airspace for IFR operations at Philippi/Barbour County Regional Airport. Designations for Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in FAA Order 7400.9R, dated August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR part 71.1. The Class E designations listed in this document will be published subsequently in the Order.

Interested parties were invited to participate in this rulemaking by submitting comments on the proposal to the FAA. No comments objecting to the proposal were received.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace at Philippi, WV, to provide controlled airspace required to support the new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAP) Runways 08–26 that have been developed for Philippi/Barbour County Regional Airport.

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

AEA WV E5 Philippi, WV [NEW]

Philippi/Barbour County Regional Airport, WV

(Lat. 39°09′58″ N, long. 80°03′45″ W)

That airspace extending upward from 700 feet above the surface of the earth within a 6.6-mile radius of Philippi/Barbour County Regional Airport.

* * * * *

Issued in College Park, Georgia, on June 4, 2008.

Mark D. Ward,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. E8–14164 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 30615; Amdt. No. 475]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: *Effective Date:* 0901 UTC, July 31, 2008.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125), telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

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

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC on June 20, 2008.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, July 31, 2008.

PART 95—[AMENDED]

■ 1. The authority citation for part 95 continues to read as follows:

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

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS
AMENDMENT 475
EFFECTIVE DATE JULY 31, 2008

From/To	Total distance	Changeover distance	Point from	Track angle	MEA	MAA
§ 95.5000 Ground-Based High Altitude RNAV Routes is Amended to Delete						
J888R						
Amott, AK RP	107.0	75	AMOTT	245/065 TO COP	28000	45000
Malos, AK WP				244/064 TO MALOS		
Malos, AK WP	59.0	32	MALOS	243/063 TO COP	28000	45000
Mousy, AK WP				241/061 TO MOUSY		
Mousy, AK WP	196.0				28000	45000
Ozzie, AK WP				230/050 TO OZZIE		
J996R						
Cape Newenham, AK					25000	45000
NDB/DME						
NERKA, AK WP						
NERKA, AK WP	129.0				18000	45000
CARBU, AK WP				047/227 TO CARBU		
CARBU, AK WP	114.0	11	CARBU	047/227 TO COP	18000	45000

FROM	TO	MEA
§ 95.1001 Direct Routes—U.S. Color Routes **§ 95.4 Green Federal Airway G2 is Amended To Read in Part**		
Borland, AK NDB/DME *6600—MOCA	Woody Island, AK NDB	*10000
§ 95.6001 Victor Routes—U.S. **§ 95.6004 VOR Federal Airway V4**		
Kansas City, MO VORTAC	Lexin, MO FIX	2600
Lexin, MO FIX *3000—GNSS MEA	Hallsville, MO VORTAC	*6000
§ 95.6026 VOR Federal Airway V26 is Amended To Read in Part		
Huron, SD VORTAC *4000—GNSS MEA	Obitt, SD FIX	*5000
Obitt, SD FIX *4000—GNSS MEA	Ghent, MN FIX	*6000
Ghent, MN FIX *4000—GNSS MEA	Redwood Falls, MN VOR/DME	*5000
§ 95.6055 VOR Federal Airway V55 is Amended To Read in Part		
Eau Claire, WI VORTAC *2800—MOCA *3000—GNSS MEA	Siren, WI VOR/DME	*5000
Siren, WI VOR/DME *2800—MOCA *3000—GNSS MEA	Brainerd, MN VORTAC	*6000
§ 95.6071 VOR Federal Airway V71 is Amended To Read in Part		
Hot Springs, AR VOR/DME *3100—MOCA	Ollas, AR FIX	*3600
Ollas, AR FIX *2500—MOCA	Haawk, AR FIX	*4500
Haawk, AR FIX *3700—MOCA *4000—GNSS MEA	Harrison, AR VOR/DME	*10000
§ 95.6077 VOR Federal Airway V77 is Amended To Read in Part		
Will Rogers, OK VORTAC	Castn, OK FIX	3500
Castn, OK FIX	Wendy, OK FIX	4000
Wendy, OK FIX	Pioneer, OK VORTAC	2900
§ 95.6082 VOR Federal Airway V82 is Amended To Read in Part		
Farmington, MN VORTAC *4000—MRA	*Cordy, MN FIX	3000

FROM	TO	MEA
*Cordy, MN FIX *4000—MRA	Rochester, MN VOR/DME	3000
§ 95.6134 VOR Federal Airway V134 is Amended To Read in Part		
Grand Junction, CO VORTAC	Paces, CO FIX	11500
Paces, CO FIX	Slolm, CO FIX	13000
Slolm, CO FIX *16000—MRA	*Gleno, CO FIX	14000
*Gleno, CO FIX *16000—MRA	Red Table, CO VOR/DME	14000
§ 95.6148 VOR Federal Airway V148 is Amended To Read in Part		
Gopher, MN VORTAC *2700—MOCA	Aleen, WI FIX	*5000
§ 95.6161 VOR Federal Airway V161 is Amended To Read in Part		
Rochester, MN VOR/DME *4000—MRA	*Cordy, MN FIX	3000
*Cordy, MN FIX *4000—MRA	Farmington, MN VORTAC	3000
§ 95.6203 VOR Federal Airway V203 is Amended To Read in Part		
Albany, NY VORTAC *2200—MOCA *3000—GNSS MEA	Otole, NY FIX	*6000
Otole, NY FIX *6900—MOCA *7000—GNSS MEA	Dinny, NY FIX	*10000
§ 95.6214 VOR Federal Airway V214 is Amended To Read in Part		
Dupont, DE VORTAC *3000—GNSS MEA	Yardley, PA VOR/DME	*6000
§ 95.6220 VOR Federal Airway V220 is Amended To Read in Part		
Grand Junction, CO VORTAC	Paces, CO FIX	11500
§ 95.6302 VOR Federal Airway V302 is Amended To Read in Part		
Augusta, ME VOR/DME *3000—GNSS MEA	Ancor, ME FIX	*5000
§ 95.6374 VOR Federal Airway V374 is Amended To Read in Part		
Carmel, NY VOR/DME	Vollu, NY FIX	2600
Vollu, NY FIX *3200—MOCA	Gayel, NY FIX	*5000
Gayel, NY FIX *6000—GNSS MEA	Binghamton, NY VORTAC	*10000
§ 95.6378 VOR Federal Airway V378 is Amended To Read in Part		
Belay, MD FIX *4000—GNSS MEA	Troyz, MD FIX	*9500
Troyz, MD FIX *4000—GNSS MEA	Nuggy, PA FIX	*7500
Nuggy, PA FIX *2000—MOCA *4000—GNSS MEA	Modena, PA VORTAC	*6000
§ 95.6403 VOR Federal Airway V403 is Amended To Read in Part		
Belay, MD FIX *2100—MOCA *3000—GNSS MEA	Spery, PA FIX	*10000
§ 95.6405 VOR Federal Airway V405 is Amended To Read in Part		
Belay, MD FIX *2100—MOCA	Spery, PA FIX	*10000

FROM	TO	MEA
*3000—GNSS MEA		
§ 95.6408 VOR Federal Airway V408 is Amended To Read in Part		
Lake Henry, PA VORTAC	Prnce, NY FIX	6000 MAA—15000
Prnce, NY FIX	Sages, NY FIX	6400 MAA—15000
§ 95.6430 VOR Federal Airway V430 is Amended To Read in Part		
Ironwood, MI VORTAC *3400—MOCA	Diner, MI FIX	*3500
Diner, MI FIX *3500—MOCA *4000—GNSS MEA	Iron Mountain, MI VOR/DME	*5000
§ 95.6431 VOR Federal Airway V431 is Amended To Read in Part		
Keene, NH VORTAC *3600—MOCA	Brats, VT FIX	*4400
Glens Falls, NY VORTAC *6000—GNSS MEA	Gassy, NY FIX	*10000
§ 95.6433 VOR Federal Airway V433 is Amended To Read in Part		
Dupont, DE VORTAC *3000—GNSS MEA	Yardley, PA VOR/DME	*6000
§ 95.6445 VOR Federal Airway V445 is Amended To Read in Part		
Dupont, DE VORTAC *3000—GNSS MEA	Yardley, PA VOR/DME	*6000
§ 95.6451 VOR Federal Airway V451 is Amended To Read in Part		
Cream, NY FIX *4000—GNSS MEA	Groton, CT VOR/DME	*6000
§ 95.6496 VOR Federal Airway V496 is Amended To Read in Part		
Mallo, NY FIX *6000—GNSS MEA	Glens Falls, NY VORTAC	*7000
Glens Falls, NY VORTAC *6000—GNSS MEA	Kerst, VT FIX	*10000
§ 95.6591 VOR Federal Airway V591 is Amended To Read in Part		
Grand Junction, CO VORTAC	Paces, CO FIX	11500
Slolm, CO FIX *16000—MRA	*Gleno, CO FIX	14000
*Gleno, CO FIX *16000—MRA	Snow, CO VOR/DME	14000
§ 95.6531 Alaska VOR Federal Airway V531 is Amended To Read in Part		
Huslia, AK VOR/DME	Atago, AK FIX	.....
	E BND	*3500
	W BND	*4000
*2500—MOCA		
Atago, AK FIX	Desoy, AK FIX	4000
Kotzebue, AK VOR/DME	Berjo, AK FIX	.....
	SE BND	*2500
	NW BND	*8000
*2500—MOCA		

[FR Doc. E8–14543 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 158 and 260

[Docket No. RM07–9–001; Order No. 710–A]

Revisions to Forms, Statements, and Reporting Requirements for Natural Gas Pipelines

Issued June 20, 2008.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Order Granting in Part and Denying in Part Rehearing and Granting Request for Clarification.

SUMMARY: In this order on rehearing, the Commission affirms its basic determinations in Order No. 710, grants in part and denies in part rehearing and grants clarification regarding certain revisions to its forms and reporting requirements for natural gas pipelines.

DATES: *Effective Date:* This Rule will become effective July 28, 2008. The revisions to FERC Form Nos. 2, 2–A, and 3–Q are applicable January 1, 2008, and February 28, 2009 for the termination of FERC Form No. 11.

FOR FURTHER INFORMATION CONTACT:

Michelle Veloso (Technical Information), Division of Financial Regulation, Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Telephone: (202) 502–8363, E-mail: *michelle.veloso@ferc.gov*.

Scott Molony (Technical Information), Chief Accountant, Division of Financial Regulation, Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Telephone: (202) 502–8919, E-mail: *scott.molony@ferc.gov*.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Joseph T. Kelliher, Chairman; Suedeen G. Kelly, Marc Spitzer, Philip D. Moeller, and Jon Wellinghoff.

1. This order addresses requests for rehearing and clarification of Order No. 710, a Final Rule issued on March 21, 2008, adopting revisions to the Commission's financial reporting requirements for natural gas pipelines, FERC Form Nos. 2, 2–A and 3–Q.[1]

I. Background

2. On September 20, 2007, the Commission issued a Notice of Proposed Rulemaking (NOPR) proposing changes to the financial forms and reporting requirements for natural gas pipelines.[2] The NOPR was issued following an in-depth review of financial reporting requirements for the natural gas, electric utility and oil pipeline industries in the fall of 2006. The staff's review, including outreach meetings with both form filers and users, culminated in the issuance of a Notice of Inquiry seeking comment on the need for changes or additions to the financial information reported in the Commission's quarterly and annual financial reports.[3]

3. The changes adopted in the Final Rule were designed to enhance the transparency of financial reporting by interstate natural gas pipelines and better reflect the current market and cost information needed for the Commission's oversight of interstate natural gas pipeline rates. The Final Rule requires the forms' filers to provide additional information on costs and revenues related to the disposition of shipper-supplied gas, affiliate transactions, discounted and negotiated rate services, and deferred income tax and state tax issues. The Final Rule eliminated FERC Form No. 11 and incorporated the information contained in that form into Form Nos. 2 and 3–Q. The revisions to Form Nos. 2, 2–A and 3–Q are applicable January 1, 2008. The revised Form Nos. 2 and 2–A are required to be filed on April 30, 2009. The termination of FERC Form No. 11 is effective February 28, 2009.

II. Requests for Rehearing and Clarification

4. Timely requests for clarification and/or rehearing were filed by the American Gas Association (AGA), Dominion Resources, Inc. (Dominion), the Interstate Natural Gas Association of America (INGAA), and the Kansas Corporation Commission (KCC).

A. Other Gas Revenues

5. INGAA and Dominion filed requests for clarification or rehearing of the elimination of an instruction on page 308 of Form Nos. 2 and 2–A. The Final Rule revised page 308 to provide more detail regarding revenues recorded in Account 495, Other Gas Revenues. Previously, pipelines were required to report this information in the aggregate and not required to include detailed information about the nature of the business activities from which the revenues are derived. The Commission determined that it was important for users of the data to understand which customer classes or groups are affected by the miscellaneous gas revenues reported in Form Nos. 2 and 2–A.[4] Accordingly, page 308 was revised to include a breakdown of the types of revenues in Account No. 495 to be separately reported on that schedule.[5]

6. Prior to the revisions adopted in the Final Rule, the instructions for page 308 did not require the revenue information to be broken down but simply stated that transactions (identified in the instructions) with annual revenues of $250,000 or more were to be reported in the aggregate. In the Final Rule, miscellaneous revenue was broken out into ten separate categories and the instructions for page 308, including the $250,000 threshold, were eliminated.[6]

7. INGAA and Dominion request that the Commission reinstate the $250,000 minimum threshold contained in the instructions to page 308 prior to revision of the forms. INGAA notes that in the Final Rule, the Commission reinstated a similar minimum threshold reporting requirement for one existing schedule and inserted the same threshold reporting requirement for another.[7] The Commission agreed with commenters who argued that the absence of such minimum thresholds could add a substantial burden to the forms' filers.[8] We grant rehearing. We agree that a similar burden could be imposed on filers absent the change sought by INGAA and Dominion. Accordingly, we will reinstate a minimum reporting threshold for page 308 and clarify that the reporting requirements for the ten categories of discrete miscellaneous revenues listed thereon be limited to transactions with annual revenues of $250,000 or greater.

B. Shipper-Supplied Gas

8. The Final Rule adopted two new schedules to require natural gas companies to provide detailed information regarding the acquisition and disposition of shipper-supplied gas.[9] The Commission noted that, despite existing accounting and reporting requirements for gas used in

[1] *Revisions to Forms, Statements, and Reporting Requirements for Natural Gas Pipelines*, Order No. 710, 73 FR 19389 (Apr. 10, 2008), FERC Stats. & Regs. ¶ 31,267 (2008) (Final Rule).

[2] *Revisions to Forms, Statements, and Reporting Requirements for Natural Gas Pipelines*, Notice of Proposed Rulemaking, 72 FR 54860 (Sept. 27, 2007), FERC Stats. & Regs. ¶ 32,623 (2007) (NOPR).

[3] *Assessment of Information Requirements for FERC Financial Forms*, Notice of Inquiry, FERC Stats. & Regs. ¶ 35,554 (2007).

[4] *See* Order No. 710 at P 19.

[5] *Id.*

[6] *Id.* at App. C, p. 308.

[7] *Id.* P 22 (pages 357–8 of Form 2).

[8] *Id.*

[9] *Id.* P 16.

operations, gas lost, and gas sold, Form Nos. 2 and 2–A users are unable to readily determine the disposition and value of shipper-supplied gas that exceeds the pipelines' operational needs or the source and cost of any gas acquired to meet deficiencies in shipper-supplied gas.[10] Given the rising cost of gas and a lack of detailed, current information, the Commission adopted new schedules for Form Nos. 2, 2–A and 3–Q to require the following information: (1) The difference between the volume of gas received from shippers and the volume of gas consumed in pipeline operations each month; (2) the disposition of any excess and the accounting recognition given to such disposition including the basis of valuing the gas and the specific accounts charged or credited; and (3) the source of gas used to meet any deficiency and the accounting recognition given to the gas used to meet the deficiency, including the accounting basis of the gas and the specific account(s) charged or credited.[11]

9. The Final Rule declined to adopt additional information requirements related to shipper-supplied gas and concluded that the requested information was already available to the forms' users or that adding requirements might upset the delicate balance between burden and benefit.[12] On rehearing, AGA argues that the Commission erred by failing to adopt AGA's suggestion that the new information reported on pages 521a and 521b of Form Nos. 2, 2–A and 3–Q should be broken down by function and include, by function, the amount of fuel that has been waived, discounted, or reduced as part of a negotiated rate agreement.[13] The Commission declined to adopt the additional detail requested by AGA, pointing out that certain fuel information, broken out by function, is already available on page 520 of Form Nos. 2 and 2–A.[14]

10. AGA's request for rehearing argues that, while page 520 of the form provides certain fuel information by function, the information is not adequate to enable a form user to determine where on the pipeline system fuel costs are being incurred and how they are being allocated.[15] As stated in the Final Rule, Page 520 of Form Nos. 2 and 2–A provides fuel losses by function (unaccounted for gas is broken out by function at lines 30–34).[16] AGA argues that additional detail regarding fuel costs is required for schedules 521a and 521b to ensure that the Commission and pipeline customers have the information required to assess the justness and reasonableness of pipeline rates.[17] The Final Rule approved extensive revisions to Form Nos. 2, 2–A and 3–Q with respect to the disposition of shipper supplied gas, adding two new schedules to the forms to accommodate the information collection.[18] INGAA and other pipeline commenters objected to the changes as burdensome, but the Commission deemed the collection of this information critical in light of the increased impact on the pipeline's cost of service as a result of rising gas prices.[19] At the same time, the Commission noted that the need to provide greater transparency with regard to fuel costs had to be balanced with the additional reporting burdens placed on the pipeline, and the Commission approved the new schedules as a fair reflection of this balance.[20] In addition, the Commission stated that some of the information sought by AGA, i.e., certain data broken out by function, is already available on page 520 of Form Nos. 2 and 2–A and the Final Rule added page 520 to Form No. 3–Q as well. While the detail sought by AGA might provide additional clarity with respect to fuel costs, we do not believe its exclusion will preclude the Commission's or customers' ability to assess the justness and reasonableness of pipeline rates.

11. We also deem unnecessary and burdensome AGA's request that pipelines provide information regarding the amount of fuel that a pipeline has waived, discounted or reduced as part of a negotiated rate agreement. AGA argues that some pipelines currently provide information in periodic fuel reports regarding fuel that has been waived, discounted, or reduced as part of a negotiated rate agreement. In support, AGA cites a fuel report filed by Dominion Transmission, Inc. (Dominion Transmission).[21] The report cited by AGA is a 20-page annual fuel report filed by Dominion Transmission pursuant to a rate settlement agreement, and exceeds, in significant detail, the type of financial and rate information the Commission deems appropriate for Forms 2, 2–A and 3–Q. It is unlikely that all pipelines would have this information readily available since many pipelines do not periodically file to adjust fuel rates and may not keep records of this type of information. Further, it is not apparent that the level of fuel associated with these types of transactions is significant enough to warrant additional reporting requirements. Customers of pipelines that use fuel tracking mechanisms and file periodic true-up reports may explore these issues in the context of the pipeline's periodic fuel filings. For these reasons, we deny AGA's request for rehearing.

C. Reinstatement of Periodic Rate Filing Requirement

12. The KCC's request for rehearing argues that the Final Rule did not address its proposal to reinstate a periodic rate-refiling requirement as a condition to issuance of a blanket certificate for open access transportation service under Part 284 of the Commission's regulations.[22] The KCC states that the Commission has the ability to impose conditions under section 7(c) of the Natural Gas Act (NGA) and that conditioning blanket certificate authority on periodic filing of general section 4 rate cases would be within the Commission's authority.[23] Further, the KCC argues that imposing such a condition would not violate the distinction between sections 4 and 5 of the NGA any more than when the Commission imposed a triennial rate filing requirement as a condition to receipt of a purchased gas adjustment (PGA) clause in pipeline tariffs.[24]

13. Contrary to KCC's claim, the Final Rule addressed its request that the Commission reinstate a periodic rate-refiling requirement.[25] It is well settled that the Commission may not compromise the limits of section 5 of the NGA on the Commission's power to revise rates.[26] The KCC's proposal is inconsistent with that limitation on the Commission's powers. In *PSCNY* v. *FERC*, the court reviewed the Commission's orders in a pipeline's first NGA section 4 rate case after it had received a certificate of public

[10] *See* NOPR at P 37.

[11] *Id.* P 39.

[12] Order No. 710 at P 16.

[13] AGA Request for Rehearing at 2.

[14] Order No. 710 at P 16.

[15] AGA Request for Rehearing at 5.

[16] Order No. 710 at P 16.

[17] *See* AGA Request for Rehearing at 5–6.

[18] *See* Order No. 710 at P 16.

[19] *Id. See also Public Service Commission of New York, Pennsylvania Public Utility Commission and Pennsylvania Office of Consumer Advocate* v. *National Fuel Gas Supply Corp.*, 115 FERC ¶ 61,299 (2006), *order approving uncontested settlement*, 118 FERC ¶ 61,091 (2007).

[20] Order No. 710 at P 16.

[21] *See* AGA Request for Rehearing at 3, citing *Dominion Transmission, Inc.*, Docket No. RP00–632–023.

[22] KCC Request for Rehearing at 8.

[23] *Id.*

[24] *Id.*

[25] *See* Order No. 710 at P 12.

[26] *Public Service Commission of New York* v. *FERC*, 866 F.2d 487, 489 (D.C. Cir. 1989) (*PSNY* v. *FERC*); *see also United Distribution Companies* v. *FERC*, 88 F.3d 1105 (D.C. Cir. 1996).

convenience and necessity pursuant to section 7 of the NGA. In those orders, the Commission approved the pipeline's proposed rates. However, because the pipeline's rate base was expected to continue declining, the Commission required that the pipeline file a new section 4 rate case every three years so as to minimize the possibility of the pipeline recovering an excessive return on equity.[27] The court rejected the Commission's decision and held that the Commission's action would destroy the balance struck by the NGA in sections 4 and 5 of the act.[28] The court further admonished the Commission that it had considered earlier efforts by the Commission to ''escape the inconveniences of § 5,'' citing *Panhandle Eastern Pipe Line Co.* v. *FERC*, 613 F.2d 1120 (D.C. Cir. 1979) (*Panhandle*). In *Panhandle*, the Commission had issued a section 7 certificate and conditioned the certificate on the pipeline's crediting revenues from the new service to customers of other pipeline services. The court labeled the condition as ''a de facto reduction in existing rates,'' and concluded that ''in light of the distinctions between §§ 4 and 5, FERC's proposed tinkering with existing rates would 'effectively emasculate the role of section 5 in the ratemaking scheme'.'' [29]

14. Along the same lines, in *United Distribution Companies* v. *FERC*, the court affirmed the Commission's refusal in Order No. 636 to impose a three-year rate review on open access pipelines with blanket certificates.[30] The court rejected the claim of those in favor of retaining triennial rate review that the market-based sales authority granted to pipelines in Order No. 636 and Straight Fixed Variable (SFV) transportation rate design required by that order are benefits to which a periodic rate filing requirement may be attached.[31] The court pointed out that pipelines were leaving the sales business, and ''whatever the benefits of SFV rate design to pipelines, they are not benefits voluntarily accepted by the pipelines and so cannot be the basis for imposition of periodic rate review.'' [32] The court also cited the decision in *PSCNY* v. *FERC* ''noting that FERC's authority to impose a periodic rate review in the PGA context 'obviously rests on pipeline consent' to triennial rate review in exchange for automatic PGA adjustment authority.'' [33]

15. The relief requested by KCC in this proceeding is the same and must be rejected for the same reasons. As the court has pointed out, the rate refiling requirement that was once imposed in exchange for the pipeline's ability to recover purchased gas costs through a tracker was based upon the voluntary acceptance by the pipeline of a rate refiling condition. In addition, allowing pipelines to track gas costs through a PGA was an exception to the Commission's general ratemaking policy that pipelines may not change individual components of their cost of service without filing a general section 4 rate case. Therefore, if a pipeline chose not to accept the option of PGA recovery of gas costs, its alternative was to adjust its rates for changes in its gas costs in a general section 4 rate case. Because that alternative was consistent with the Commission's general ratemaking policy, it was as consistent with the public interest as the PGA recovery option. KCC's proposal is dissimilar in both respects. In today's natural gas market, open access transportation is so fundamental to the manner in which pipelines conduct business that there is no realistic option for a pipeline not to retain its blanket certificate. The alternative would require a return to the pre-open access past when pipelines provided only individually certificated service requiring abandonment proceedings under section 7 of the NGA and would deprive the pipeline's customers and the public at large of the many benefits of open access transportation service. It is unlikely that a pipeline would ''voluntarily'' consent to such a condition and, in any event, the pipeline's alternative of discontinuing open access transportation service would not be in the public interest.

16. The revisions to Form Nos. 2, 2–A and 3–Q adopted in the Final Rule were designed to provide a level of information that would enhance the ability of the Commission and pipeline customers to assess the justness and reasonableness of pipeline rates. As we stated in the Final Rule, the Commission cannot compel a pipeline to file a rate case under section 4, nor can it preclude it from filing under section 4 for any reason.[34] The Commission's efforts in this regard reflect its awareness that pipeline customers need additional information to make a reasonable assessment of a pipeline's cost of service, and we believe that the Final Rule accomplishes that goal. Accordingly, we deny the KCC's request for rehearing.

D. Miscellaneous

17. Following the issuance of the Final Rule, staff discovered a few inadvertent errors in two of the revised schedules, pages 278 and 299. These revisions are for purposes of clarification and do not affect the level of information requested in the forms.

18. Column (a) on page 278 is revised to reference liabilities rather than assets. The column labeled ''Written off During Quarter/Year Account Charged'' replaces the word ''charged'' with ''credited.'' The column labeled ''Debits'' is revised to read ''Credits.''

19. The instructions to page 299, Monthly Quantity & Revenue Data by Rate Schedule are revised as reflected on the attached schedule.

The Commission Orders

The requests for clarification and/or rehearing are granted in part and denied in part as discussed in the body of this order.

By the Commission. Commissioner Wellinghoff dissenting in part with a separate statement attached.

Kimberly D. Bose,

Secretary.

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[27] *PSNY* v. *FERC*, 866 F.2d at 490.

[28] *Id.*

[29] *PSCNY* v. *FERC*, 866 F.2d at 490. *See also Northern Natural Gas Co.* v. *FERC*, 780 F.2d 59 (D.C. Cir. 1985).

[30] *United Distribution Cos.* v. *FERC*, 88 F.3d 110, 1175–6.

[31] *Id.* at 1176.

[32] *Id.* at 1176.

[33] *Id.* at 1176, citing *PSCNY* v. *FERC*, 866 F.2d at 492.

[34] Order No. 710 at P 12.

Revised Schedules for FERC Forms 2,2-A, and 3-Q

Name of Respondent	This Report is: (1) An Original (2) A Resubmission	Date of Report (Mo. Da. Yr.	Year/Period of Report End of Year/Qtr

Other Regulatory Liabilities (Account 254)

1. Report below the details called for concerning other regulatory liabilities which are created through the ratemaking actions of regulatory agencies (and not includable in other accounts).
2. For regulatory assets being amortized, show the period of amortization in column (a).
3. Minor items (5% of the Balance at the End of the Year for Account 182.3 or amounts less than $250,000, whichever is less) may be grouped by classes.
4. Provide in a footnote, for each line item, the regulatory citation where the respondent was directed to refund the regulatory liability (e.g. Commission Order, state commission order, court decision.

Line No.	Description and Purpose of Other Regulatory Liabilities (a)	Balance at Beginning Current of Quarter/Year (b)	Written off During Quarter/Year Account Credited (c)	Written Off During the Period		Credits (f)	Balance at End of Current Quarter/Year (g)
				Amount Refunded (d)	Amount Deemed Non-Refundable (e)		
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3							
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39							
40							
41	Total						

Revised Schedules for FERC Forms 2,2-A, and 3-Q

Name of Respondent	This Report is: (1) An Original (2) A Resubmission	Date of Report (Mo. Da. Yr.	Year/Period of Report End of Year/Qtr

Monthly Quantity & Revenue Data by Rate Schedule

Select the appropriate Month from the dropdown menu.

1. Reference to account numbers in the USofA is provided in parentheses beside applicable data. Quantities must not be adjusted for discounts.
2. Total Quantities and Revenues in whole numbers
3. Report revenues and quantities of gas by rate schedule. Where transportation services are bundled with storage services, reflect only transportation Dth. When reporting storage, report Dth of gas withdrawn from storage and revenues by rate schedule.
4. Revenues in Column (c) include transition costs from upstream pipelines. Revenue (Other) in Column (e) includes reservation charges received by the pipeline plus usage charges, less revenues reflected in Columns (c) and (d). Include in Column (e), revenue for Accounts 490-495.
5. Enter footnotes as appropriate.
6. Select the appropriate Month from the dropdown menu.

Line No.	Item (a)	Quantity (b)	Revenue Transition Costs and Take-or-Pay (c)	Revenue (GRI & ACA) (d)	Revenue (Other) (e)	Revenue (Total) (f)
1	Total Sales (480-488)					
2	Transportation of Gas for Others (489.2 and 489.3)					
2.001	[Rate Schedule Number]					
2.002	[Rate Schedule Number]					
2.003	[Rate Schedule Number]					
2.004	[Rate Schedule Number]					
2.005	[Rate Schedule Number]					
2.006	[Rate Schedule Number]					
2.007	[Rate Schedule Number]					
2.008	[Rate Schedule Number]					
2.009	[Rate Schedule Number]					
2.010	[Rate Schedule Number]					
3	Total Transportation (Other than Gathering)					
4	Storage (489.4)					
4.001	[Rate Schedule Number]					
4.002	[Rate Schedule Number]					
4.003	[Rate Schedule Number]					
4.004	[Rate Schedule Number]					
4.005	[Rate Schedule Number]					
5	Total Storage					
6	Gathering (489.1)					
7	Gathering-Firm					
8	Gathering-Interruptible					
9	Total Gathering (489.1)					
10	Additional Revenues					
11	Products Sales and Extraction (490-492)					
12	Rents (493-494)					
13	Other Gas Revenues (495)					
14	(Less) Provision for Rate Refunds					
15	Total Additional Revenues					
16	Total Operating Revenues (Total of Lines 1, 3, 5, 9, and 15					

Revised Schedules for FERC Forms 2,2-A, and 3-Q

Name of Respondent	This Report is: (1) An Original (2) A Resubmission	Date of Report (Mo. Da. Yr.	Year/Period of Report End of Year/Qtr

Other Gas Revenues (Account 495)

Report below transactions of $250,000 or more included in Account 495, Other Gas Revenues. Group all transactions below $250,000 in one amount and provide the number of items.

Line No.	Description of Transaction (a)	Amount (b)
1	Commissions on Sale or Distribution of Gas of Others	
2	Compensation for Minor or Incidental Services Provided for Others	
3	Profit or Loss on Sale of Material and Supplies not Ordinarily Purchased for Resale	
4	Sales of Stream, Water, or Electricity, including Sales or Transfers to Other Departments	
5	Miscellaneous Royalties	
6	Revenues from Dehydration and Other Processing of Gas of Others except as provided for in the Instructions to Account 495	
7	Revenues for Right and/or Benefits Received from Others which are Realized Through Research, Development, and Demonstration Ventures	
8	Gains on Settlements of Imbalance Receivables and Payables	
9	Revenues from Penalties earned Pursuant to Tariff Provisions, including Penalties Associated with Cash-out Settlements	
10	Revenues from Shipper Supplied Gas	
11	Other revenues (Specify):	
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50		
51		
52	**Total**	

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WELLINGHOFF, Commissioner, *dissenting in part:*

On rehearing, the American Gas Association (AGA) continues to recommend that the Commission require pipelines to provide shipper-supplied gas information reported on Sheets 521a/b by function and to include, by function, the amount of fuel that has been waived, discounted or reduced as part of a negotiated rate agreement. The Commission rejects AGA's proposals. I disagree.

In denying the request for shipper-supplied gas information reported on Sheets 521a/b by function, the majority acknowledges that the detail sought by AGA would bring additional clarity to fuel costs. However, the majority states that the additional information is not needed to assess the justness and reasonableness of the pipeline's rates. The majority further states that the additional reporting would be too burdensome.

The Commission recognizes that shipper-supplied gas information is critical to the clarity and transparency needed to support a reasonable analysis of fuel gas costs.[35] Sheets 521a/b operate in tandem with Sheet 520. Sheet 520 provides fuel gas costs by function. A shipper pays for fuel costs by function whether the fuel rate is fixed or tracked. Sheets 521a/b provide the volume and revenue from the disposition of excess shipper-supplied gas. However, unless Sheets 521a/b are broken out by function, a shipper cannot match the revenues generated by the sale of excess fuel with the functionalized costs. Thus, because the fuel rate would include both gas costs and excess gas revenues, the information sought by AGA is critical to assessing the justness and reasonableness of the pipeline's fuel rates.

In denying the request for the amount of fuel by function that has been waived, discounted or reduced as part of a negotiated rate agreement, the majority states that it is unlikely that all pipelines would have this information readily available. The majority also asserts that it is not apparent that the level of fuel associated with these types of transactions is significant enough to warrant additional reporting.

With most pipeline expansions backstopped with negotiated rate contracts, I believe that the fuel associated with these types of transactions is not insignificant. Regardless of the level of fuel, the Commission has a strict policy that existing shippers must not subsidize the negotiated rate program.[36] In fact, in this proceeding, the Commission has stated that because pipelines may provide services from the same facilities using different rates—negotiated, discounted or recourse rates—it is important to know the level of services provided under each rate structure in order to protect against cross-subsidization. Therefore, fuel costs and revenues of the different types of rate structures broken down by function are critical to assessing the justness and reasonableness of a pipeline's fuel rates.

With regard to the reporting burden, the information requested by AGA is readily available. The pipeline maintains this information by function in order to change its fuel rate either in a tracking mechanism or its next section 4 rate filing, and to assure that its existing customers are not subsidizing the negotiated rate program.[37] The increased burden is related solely to inputting the data in the Form 2. I believe that the increased burden is justified by the utility of the information.

For these reasons, I respectfully dissent in part from today's order.

Jon Wellinghoff,

Commissioner.

[FR Doc. E8–14463 Filed 6–26–08; 8:45 am]

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[35] *Revisions to Forms, Statements, and Reporting Requirements for Natural Gas Pipelines*, Order No. 710, 73 FR 19389 (Apr. 10, 2008), FERC Stats. & Regs. ¶ 31,267 (2008).

[36] *See Alternative Rate Policy Statement*, 74 FERC ¶ 61,076 at 61,242 (1996), and *NorAm Gas Transmission Company*, 77 FERC ¶ 61,011 (1996).

[37] *See Alternative Rate Policy Statement*, 74 FERC ¶ 61,076 at 61,241 (1996).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9404]

RIN 1545–BE97

Capital Costs Incurred To Comply With EPA Sulfur Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations relating to the deduction provided under section 179B of the Internal Revenue Code (Code) for qualified capital costs paid or incurred by a small business refiner to comply with the highway diesel fuel sulfur control requirements of the Environmental Protection Agency (EPA). The regulations implement changes to the law made by the American Jobs Creation Act of 2004, the Energy Policy Act of 2005, and the Tax Technical Corrections Act of 2007. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on June 27, 2008.

Applicability Date: For dates of applicability, see § 1.179B–1T(f).

FOR FURTHER INFORMATION CONTACT: Nicole Cimino, (202) 622–3110 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These temporary regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these regulations has been reviewed and pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545–2104. Responses to this collection of information are required to obtain a tax benefit.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

For further information concerning this collection of information, and where to submit comments on the collection of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-referencing notice of proposed rulemaking published in the Proposed Rules section in this issue of the **Federal Register**.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains amendments to 26 CFR part 1 providing temporary regulations under section 179B of the Code. Section 179B was added to the Code by section 338(a) of the American Jobs Creation Act of 2004, Public Law 108–357 (118 Stat. 1418), and was modified by section 1324(a) of the

Energy Policy Act of 2005, Public Law 109–58 (119 Stat. 594), and the Tax Technical Corrections Act of 2007, Public Law 110–172 (121 Stat. 2473).

In general, the cost of property used in a trade or business or held for the production of income must be capitalized and, in the case of depreciable property, recovered through depreciation. Section 167 allows as a depreciation deduction a reasonable allowance for the exhaustion, wear, and tear of property used in a trade or business or held for the production of income. The depreciation allowable for tangible, depreciable property placed in service after 1986 generally is determined under section 168.

In lieu of deducting depreciation, section 179B(a) allows a small business refiner to deduct as an expense 75 percent of the qualified costs as defined in section 45H(c)(2) that are paid or incurred during the taxable year and are properly chargeable to capital account (''qualified capital cost''). Section 45H(c)(2) defines qualified costs as those costs paid or incurred during the applicable period to comply with the highway diesel fuel sulfur control requirements of the EPA (the ''applicable EPA regulations''). The deduction is phased out for refiners whose production in calendar year 2002 exceeded a specified threshold. Section 179B applies to expenses paid or incurred after December 31, 2002, in taxable years ending after December 31, 2002.

In addition, section 45H allows a production credit of five cents per gallon for low sulfur diesel fuel produced by a small business refiner. The aggregate credit claimed by a small business refiner for all taxable years may not exceed 25 percent of the qualified costs paid or incurred by the small business refiner. The aggregate allowable credit is also phased out for refiners whose production in calendar year 2002 exceeded a specified threshold. The credit is not allowed unless Treasury certifies, after consultation with EPA, that the refiner's qualified costs will result in compliance with the applicable EPA regulations. Section 280C(d) provides for the reduction, by the amount of the credit determined under section 45H(a) for the taxable year, in deductions otherwise allowable for the taxable year under subtitle A, Chapter 1 of the Internal Revenue Code (sections 1 through 1400T). Section 45H applies to expenses paid or incurred after December 31, 2002, in taxable years ending after December 31, 2002.

Section 45H(c) provides definitions of terms for purposes of both the section 179B deduction and the section 45H credit. Under section 45H(c)(1), a taxpayer is a small business refiner for a taxable year if (i) the taxpayer is a refiner of crude oil with respect to which not more than 1,500 individuals are engaged in the refinery operations of the business on any day during the taxable year, and (ii) the taxpayer's average daily domestic refinery run or average retained production for all facilities of the taxpayer for the 1-year period ending on December 31, 2002, did not exceed 205,000 barrels. Under section 45H(c)(2), the qualified costs with respect to any facility of a small business refiner are, in general, costs that are paid or incurred by the small business refiner to comply with the applicable EPA regulations with respect to the facility during the period beginning on January 1, 2003, and ending on the earlier of the date that is one year after the date on which the small business refiner must comply with the applicable EPA regulations for that facility, or December 31, 2009.

The applicable EPA regulations are the regulations establishing the highway diesel fuel sulfur control program and apply to, among others, petroleum refiners that produce diesel fuel for heavy-duty highway vehicles. The regulations provide that these vehicles for the 2007 and later model years must be fueled with highway diesel fuel that meets a maximum sulfur standard of 15 parts per million (ppm). The regulations also require refiners to produce this new low sulfur diesel fuel beginning on June 1, 2006, but include several transition rules under which refiners are given additional time to comply with the 15 ppm sulfur standard (for example, the small refiner credit option for a refiner that is granted small refiner status by the EPA).

Explanation of Provisions

Scope

The temporary regulations provide rules prescribing how a small business refiner must determine the deduction allowable under section 179B(a) for any taxable year. The regulations also provide guidance for making the elections under section 179B.

Computation of Deduction Allowable Under Section 179B

The deduction under section 179B is allowable with respect to the qualified capital costs paid or incurred by a small business refiner during the taxable year. The temporary regulations make it clear that the deduction is allowable with respect to costs paid or incurred during a taxable year even if the property to which the costs relate is not placed in service until a subsequent taxable year. The temporary regulations also make it clear that the deduction is allowable even if the small business refiner is not eligible for the credit under section 45H because of a failure to obtain the certification required by section 45H(e).

Elections

Section 179B provides two elections. The first election is provided under section 179B(a), which allows a small business refiner to elect to deduct an amount equal to 75 percent of the qualified capital costs paid or incurred by the small business refiner during the taxable year. These temporary regulations provide that this election is made for each taxable year in which the taxpayer seeks to deduct qualified capital costs under section 179B. The election for a taxable year applies to all qualified capital costs paid or incurred by the small business refiner during the taxable year. The election for a taxable year must be made by the due date (including extensions) for filing the small business refiner's Federal income tax return for the taxable year.

The second election is provided under section 179B(e). Section 179B(e) provides that if a small business refiner is a cooperative and makes an election under section 179B(a), the small business refiner may elect to allocate part or all of the deduction allowable under section 179B(a) for the taxable year to its owners that are themselves cooperatives. If a cooperative small business refiner makes the section 179B(e) election, the temporary regulations provide that the deduction amount allocated to an owner is equal to the owner's ratable share of the total deduction amount allocated, determined on the basis of ownership interests in the cooperative small business refiner. The temporary regulations provide that in cases in which ownership interests vary during the year, the small business refiner must determine ratable shares under a consistently applied method that reasonably takes into account the varying interests during the taxable year. Further, the temporary regulations clarify that, in computing its taxable income under section 1382, the cooperative small business refiner must reduce its section 179B deduction by the deduction amount allocated to its owners.

The section 179B(e) election for a taxable year is made by the due date (including extensions) for filing the cooperative small business refiner's Federal income tax return for the taxable year. In addition, section

179B(e)(3) requires the electing cooperative small business refiner to notify, in writing, each cooperative owner of the amount of the section 179B(a) deduction that is allocated to that cooperative owner. This written notice must be mailed to the cooperative owner before the due date (including extensions) of the cooperative small business refiner's Federal income tax return.

Effective/Applicability Date

These temporary regulations apply to taxable years ending on or after *June 26, 2008*. However, a taxpayer may apply the temporary regulations to taxable years ending after December 31, 2002, and before *June 26, 2008* provided that the taxpayer applies all provisions in these regulations (other than those relating to elections) to the taxable year. A taxpayer applying the regulations to those years may make the election under section 179B(a) for such years under the rules provided in Notice 2006–47 (2006–20 IRB 892). In addition, the taxpayer's election under section 179B(e) for those years will be accepted if made using any reasonable method consistent with the principles of section 179B(e). See § 601.601(d)(2)(ii)(*b*) of this chapter.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6), please refer to the Special Analyses section of the preamble to the cross-reference notice of proposed rulemaking published in the Proposed Rules section in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Nicole R. Cimino, Office of Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

■ Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.179B–1T is added to read as follows:

§ 1.179B–1T Deduction for capital costs incurred in complying with Environmental Protection Agency sulfur regulations (temporary).

(a) *Scope and definitions*—(1) *Scope*. This section provides the rules for determining the amount of the deduction allowable under section 179B(a) for qualified capital costs paid or incurred by a small business refiner to comply with the highway diesel fuel sulfur control requirements of the Environmental Protection Agency (EPA). This section also provides rules for making elections under section 179B.

(2) *Definitions*. For purposes of section 179B and this section, the following definitions apply:

(i) The *applicable EPA regulations* are the EPA regulations establishing the highway diesel fuel sulfur control program (40 CFR part 80, subpart I).

(ii) The *average daily domestic refinery run* for a refinery is the lesser of—

(A) The total amount of crude oil input (in barrels) to the refinery's domestic processing units during the 1-year period ending on December 31, 2002, divided by 365; or

(B) The total amount of refined petroleum product (in barrels) produced by the refinery's domestic processing units during such 1-year period divided by 365.

(iii) The *aggregate average domestic daily refinery run* for a refiner is the sum of the average daily domestic refinery runs for all refineries that were owned by the refiner or a related person on April 1, 2003.

(iv) *Cooperative owner* is a person that—

(A) Directly holds an ownership interest in a cooperative small business refiner, as defined in paragraph (a)(2)(v) of this section; and

(B) Is a cooperative to which part 1 of subchapter T of the Internal Revenue Code (Code) applies.

(v) *Cooperative small business refiner* is a small business refiner that is a cooperative to which part 1 of subchapter T of the Code applies.

(vi) *Low sulfur diesel fuel* has the meaning prescribed in section 45H(c)(5).

(vii) *Qualified capital costs* are qualified costs as defined in section 45H(c)(2) that are properly chargeable to capital account.

(viii) *Related person* has the meaning prescribed in section 613A(d)(3) and the regulations under section 613A(d)(3).

(ix) *Small business refiner* has the meaning prescribed in section 45H(c)(1).

(b) *Section 179B deduction*—(1) *In general*. Section 179B(a) allows a deduction with respect to the qualified capital costs paid or incurred by a small business refiner (the section 179B deduction). The deduction is allowable with respect to the qualified capital costs paid or incurred during a taxable year only if the small business refiner makes an election under paragraph (d) of this section for the taxable year. The certification requirement in section 45H(e) (relating to the certification required to support a credit under section 45H) does not apply for purposes of the section 179B deduction. Accordingly, the section 179B deduction is allowable with respect to the qualified capital costs of an electing small business refiner even if the refiner never obtains a certification under section 45H(e) with respect to those costs.

(2) *Computation of section 179B deduction*—(i) *In general*. Except as provided in paragraphs (b)(2)(ii) and (c)(3) of this section, a small business refiner that makes an election under paragraph (d) of this section for a taxable year is allowed a section 179B deduction in an amount equal to 75 percent of qualified capital costs that are paid or incurred by the small business refiner during the taxable year.

(ii) *Reduced percentage*. A small business refiner's section 179B deduction is reduced if the refiner's aggregate average daily domestic refinery run is in excess of 155,000 barrels. In that case, the number of percentage points used in computing the deduction under paragraph (b)(2)(i) of this section (75) is reduced (not below zero) by the product of 75 and the ratio of the excess barrels to 50,000 barrels.

(3) *Example*. The application of this paragraph (b) is illustrated by the following example:

Example. (i) A, an accrual method taxpayer, is a small business refiner with a

taxable year ending December 31. On April 1, 2003, A owns a refinery with an average daily domestic refinery run (that is, an average daily run during calendar year 2002) of 100,000 barrels and a person related to A owns a refinery with an average daily domestic refinery run of 85,000 barrels. These are the only domestic refineries owned by A and persons related to A. A's aggregate average daily domestic refinery run for the two refineries is 185,000 barrels. A incurs qualified capital costs of $10 million in the taxable year ended December 31, 2007. The costs are incurred with respect to property that is placed in service in year 2008. A makes the election under paragraph (d) of this section for the 2007 taxable year.

(ii) Because A's aggregate average daily domestic refinery run is 185,000 barrels, the percentage of the qualified capital costs that is deductible under section 179B(a) is reduced from 75 percent to 30 percent (75 percent reduced by 75 percent multiplied by 0.6 ((185,000 barrels minus 155,000 barrels)/50,000 barrels)). Thus, for 2007, A's deduction under section 179B(a) is $3,000,000 ($10,000,000 qualified capital costs multiplied by .30).

(c) *Effect on basis*—(1) *In general*. If qualified capital costs are included in the basis of property, the basis of the property is reduced by the amount of the section 179B deduction allowed with respect to such costs.

(2) *Treatment as depreciation*. If qualified capital costs are included in the basis of depreciable property, the amount of the section 179B deduction allowed with respect to such costs is treated as a depreciation deduction for purposes of section 1245.

(d) *Election to deduct qualified capital costs*—(1) *In general*—(i) *Section 179B election*. This paragraph (d) prescribes rules for the election to deduct the qualified capital costs paid or incurred by a small business refiner during a taxable year (the section 179B election). A small business refiner making the section 179B election for a taxable year consents to, and agrees to apply, all of the provisions of section 179B and this section to qualified capital costs paid or incurred by the refiner during the taxable year. The section 179B election for a taxable year applies with respect to all qualified capital costs paid or incurred by the small business refiner during that taxable year.

(ii) *Year-by-year election*. A separate section 179B election must be made for each taxable year in which the taxpayer seeks to deduct qualified capital costs under section 179B. A small business refiner may make the section 179B election for some taxable years and not for other taxable years.

(iii) *Elections for cooperative small business refiners*. See paragraph (e) of this section for the rules applicable to the election provided under section 179B(e), relating to the election to allocate the section 179B deduction to cooperative owners of a cooperative small business refiner (the section 179B(e) election).

(2) *Time and manner for making section 179B election*—(i) *Time for making election*. Except as provided in paragraph (d)(2)(iii) of this section, a taxpayer's section 179B election for a taxable year must be made by the due date (including extensions) for filing the taxpayer's Federal income tax return for the taxable year.

(ii) *Manner of making election*—(A) *In general*. Except as provided in paragraph (d)(2)(iii) of this section, the section 179B election for a taxable year is made by claiming a section 179B deduction on the taxpayer's original Federal income tax return for the taxable year and attaching the statement described in paragraph (d)(2)(ii)(B) of this section to the return. The section 179B election with respect to qualified capital costs paid or incurred by a partnership is made by the partnership and the section 179B election with respect to qualified capital costs paid or incurred by an S corporation is made by the S corporation. In the case of qualified capital costs paid or incurred by the members of a consolidated group (within the meaning of § 1.1502–1(h)), the section 179B election with respect to such costs is made for each member by the common parent of the group.

(B) *Information required in election statement*. The election statement attached to the taxpayer's return must contain the following information:

(*1*) The name and identification number of the small business refiner.

(*2*) The amount of the qualified capital costs paid or incurred during the taxable year for which the election is made.

(*3*) The aggregate average daily domestic refinery run (as determined under paragraph (a)(2)(iii) of this section).

(*4*) The date by which the small business refiner must comply with the applicable EPA regulations. If this date is not June 1, 2006, the statement also must explain why compliance is not required by June 1, 2006.

(*5*) The calculation of the section 179B deduction for the taxable year.

(*6*) For each property that will have its basis reduced on account of the section 179B deduction for the taxable year, a description of the property, the amount included in the basis of the property on account of qualified capital costs paid or incurred during the taxable year, and the amount of the basis reduction to that property on account of the section 179B deduction for the taxable year.

(iii) Except as otherwise expressly provided by the Code, the regulations under the Code, or other guidance published in the Internal Revenue Bulletin, a section 179B election is valid only if made at the time and in the manner prescribed in this paragraph (d)(2). For example, except as otherwise expressly provided, the 179B election cannot be made for a taxable year to which this section applies through a request under section 446(e) to change the taxpayer's method of accounting.

(3) *Revocation of election*. An election made under this paragraph (d) may not be revoked without the prior written consent of the Commissioner of Internal Revenue. To seek the Commissioner's consent, the taxpayer must submit a request for a private letter ruling (for further guidance, see, for example, Rev. Proc. 2008–1 (2008–1 IRB 1) and § 601.601(d)(2)(ii)(*b*) of this chapter).

(4) *Failure to make election*. If a small business refiner does not make the section 179B election for a taxable year at the time and in the manner prescribed in paragraph (d)(2) of this section, no deduction is allowed for the qualified capital costs that the refiner paid or incurred during the year. Instead these qualified capital costs are chargeable to a capital account in that taxable year, the basis of the property to which these costs are capitalized is not reduced on account of section 179B, and the amount of depreciation allowable for the property attributable to these costs is determined by reference to these costs unreduced by section 179B.

(5) *Elections for taxable years ending before June 26, 2008*. This section does not apply to section 179B elections for taxable years ending before June 26, 2008. The rules for making the section 179B election for a taxable year ending before June 26, 2008 are provided in Notice 2006–47 (2006–20 IRB 892). See § 601.601(d)(2)(ii)(*b*) of this chapter.

(e) *Election under section 179B(e) to allocate section 179B deduction to cooperative owners*—(1) *In general*. A cooperative small business refiner may elect to allocate part or all of its cooperative owners' ratable shares of the section 179B deduction for a taxable year to the cooperative owners (the section 179B(e) election). The section 179B deduction allocated to a cooperative owner is equal to the cooperative owner's ratable share of the total section 179B deduction allocated. A cooperative owner's ratable share is determined for this purpose on the basis of the cooperative owner's ownership interest in the cooperative small business refiner during the cooperative

small business refiner's taxable year. If the cooperative owners' interests vary during the year, the cooperative small business refiner shall determine the owners' ratable shares under a consistently applied method that reasonably takes into account the owners' varying interests during the taxable year.

(2) *Cooperative small business refiner denied section 1382 deduction for allocated portion.* In computing taxable income under section 1382, a cooperative small business refiner must reduce its section 179B deduction for the taxable year by an amount equal to the section 179B deduction allocated under this paragraph (e) to the refiner's cooperative owners for the taxable year.

(3) *Time and manner for making election*—(i) *Time for making election.* The section 179B(e) election for a taxable year must be made by the due date (including extensions) for filing the cooperative small business refiner's Federal income tax return for the taxable year.

(ii) *Manner of making election.* The section 179B(e) election for a taxable year is made by attaching a statement to the cooperative small business refiner's Federal income tax return for the taxable year. The election statement must contain the following information:

(A) The name and identification number of the cooperative small business refiner.

(B) The amount of the section 179B deduction allowable to the cooperative small business refiner for the taxable year (determined before the application of section 179B(e) and this paragraph (e)).

(C) The name and identification number of each cooperative owner to which the cooperative small business refiner is allocating all or some of the section 179B deduction.

(D) The amount of the section 179B deduction that is allocated to each cooperative owner listed in response to paragraph (e)(3)(ii)(C) of this section.

(4) *Irrevocable election.* A section 179B(e) election for a taxable year, once made, is irrevocable for that taxable year.

(5) *Written notice to owners.* A cooperative small business refiner that makes a section 179B(e) election for a taxable year must notify each cooperative owner of the amount of the section 179B deduction that is allocated to that cooperative owner. This notification must be provided in a written notice that is mailed by the cooperative small business refiner to its cooperative owner before the due date (including extensions) of the cooperative small business refiner's Federal income tax return for the election year. In addition, the cooperative small business refiner must report the amount of the cooperative owner's section 179B deduction on Form 1099–PATR, ''Taxable Distributions Received From Cooperatives,'' issued to the cooperative owner. If Form 1099–PATR is revised or renumbered, the amount of the cooperative owner's section 179B deduction must be reported on the revised or renumbered form.

(f) *Effective/applicability date*—(1) *In general.* This section applies to taxable years ending on or after June 26, 2008.

(2) *Application to taxable years ending before June 26, 2008.* A small business refiner may apply this section to a taxable year ending before June 26, 2008, provided that the small business refiner applies all provisions in this section, with the modifications described in paragraph (f)(3) of this section, to the taxable year.

(3) *Modifications applicable to taxable years ending before June 26, 2008.* The following modifications to the rules of this section apply to a small business refiner that applies those rules to a taxable year ending before *June 26, 2008*:

(i) *Rules relating to section 179B election.* The section 179B election for a taxable year ending before *June 26, 2008* may be made under the rules provided in Notice 2006–47, rather than under the rules set forth in paragraph (d) of this section.

(ii) *Rules relating to section 179B(e) election.* A section 179B(e) election for a taxable year ending before *June 26, 2008* will be treated as satisfying the requirements of paragraph (f) if the cooperative small business refiner has calculated its tax liability in a manner consistent with the election and has used any reasonable method consistent with the principles of section 179B(e) to inform the Internal Revenue Service that an election has been made under section 179B(e) and to inform cooperative owners of the amount of the section 179B deduction they have been allocated.

(4) *Expiration date.* The applicability of § 179B–1T expires on *June 24, 2011.*

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 3.** The authority citation for part 602 continues to read as follows:

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

■ **Par. 4.** In § 602.101, paragraph (b) is amended by adding the following entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.179B–1T	1545–2076
* * * * *	

Kevin M. Brown,

Deputy Commissioner for Services and Enforcement.

Approved: June 15, 2007.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[Editorial Note: This document was *received* at the **Federal Register** on June 23, 2008.]

[FR Doc. E8–14556 Filed 6–26–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0096]

RIN 1625–AA00

Safety Zone; Festival of Sail 2008 Ship's Parade; San Diego Harbor, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone, on the navigable waters of San Diego Bay in support of the Festival of Sail 2008 Ship's Parade. This temporary safety zone is necessary to provide for the safety of the participants, crew, spectators, participating vessels, and other vessels and users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: This rule is effective from 10 a.m. until 1 p.m. on August 20, 2008.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2008–0096 and are available online at *http://*

www.regulations.gov. This material is also available for inspection or copying at two locations: the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays and the U.S. Coast Guard Sector San Diego, 2710 N. Harbor Drive, San Diego, CA 92101 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Petty Officer Kristen Beer, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at (619) 278–7233. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 23, 2008, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Festival of Sail 2008 Ship's Parade; San Diego Harbor, San Diego, CA in the **Federal Register** (73 FR 21880). We received no letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The Maritime Museum of San Diego is sponsoring the Festival of Sail 2008 Ship's Parade, which will transit through San Diego Bay. The event is a classic naval review consisting of 15 tall ships of various classes, some of which are restricted in their maneuverability. The sponsor will provide 16 enforcement vessels to patrol this event. This temporary safety zone is necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and other users of the waterway.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary.

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

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in the San Diego Bay from 10 a.m. to 1 p.m. on August 20, 2008.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. This rule will be in effect for only three hours for a period of one day. Vessel traffic can pass safely around the safety zone. Before the effective period, the Coast Guard will publish a local notice to mariners (LNM) and will issue broadcast notice to mariners (BNM) alerts via marine channel 16 VHF before the safety zone is enforced.

Assistance for Small Entities

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

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

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded, under the Instruction, that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

A final environmental analysis checklist and a final categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

Words of Issuance and Proposed Regulatory Text

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. A new temporary § 165.T11–014 to read as follows:

§ 165.T11–014 Safety Zone; Festival of Sail 2008 Ship's Parade; San Diego Harbor, San Diego, CA.

(a) *Location.* The limits of the moving safety zone are as follows: The route would start at 32°37.15′ N, 117°14.07′ W and would proceed northeast between green Buoy #3 and red Buoy #4 at 32°38.12′ N, 117°13.74′ W, then north between green Buoy #5 and red Buoy #6 at 32°39.14′ N, 117°13.51′ W, then north through the harbor channel to 32°42.07′ N, 117°13.90′ W, and then northeast to 32°43.11′ N, 117°12.71′ W, and then east to 32°43.13′ N, 117°11.12′ W, and finally southeast to the Coronado Bridge at 32°41.45′ N, 117°09.18′ W. The safety zone will encompass 1000 yards forward, 200 yards each side, and 500 yard aft of each vessel participating in the parade.

(b) *Enforcement Period.* This section will be enforced from 10 a.m. to 1 p.m. on August 20, 2008. If the event concludes prior to the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

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

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

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

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

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

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

Dated: June 10, 2008.

C. V. Strangfeld,

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

[FR Doc. E8–14512 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0180]

RIN 1625–AA00

Safety Zone; Patapsco River, Northwest and Inner Harbors, Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone upon certain waters of the Patapsco River, Northwest Harbor and Inner Harbor during the movements of the historic sloop-of-war USS CONSTELLATION. This action is necessary to provide for the safety of life on navigable waters during two tows of the vessel in Baltimore, Maryland; one from its berth at Baltimore's Inner Harbor to a berth at the South Locust Point Marine Terminal, and the other from the South Locust Point Marine Terminal to its berth at Baltimore's Inner Harbor. This action will restrict

vessel traffic in portions of the Patapsco River, Northwest Harbor, and Inner Harbor during these events.

DATES: This rule is effective from 5 p.m. on August 8, 2008 through 11 a.m. on August 10, 2008.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2008–0180 and are available online at *http://www.regulations.gov.* This material is also available for inspection or copying at two locations: The Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays and the Commander, U.S. Coast Guard Sector Baltimore, 2401 Hawkins Point Road, Building 70, Waterways Management Division, Baltimore, Maryland 21226–1791 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Mr. Ronald Houck, at Coast Guard Sector Baltimore, Waterways Management Division, at telephone number (410) 576–2674 or (410) 576–2693. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 15, 2008, we published a notice of proposed rulemaking (NPRM) entitled ''Safety Zone; Patapsco River, Northwest and Inner Harbors, Baltimore, MD'' in the **Federal Register** (73 FR 20220). We received no letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The USS CONSTELLATION Museum is planning to conduct a ceremony in the Port of Baltimore, Maryland, involving the sloop-of-war USS CONSTELLATION on Friday, August 8, 2008. Scheduled events include a four-hour tow of the USS CONSTELLATION beginning at 6 p.m., from its berth at Pier 1 Inner Harbor to the Locust Point Cruise Ship Terminal berth at the South Locust Point Marine Terminal, with an onboard salute with navy pattern cannon while the historic vessel is positioned off Fort McHenry National Monument and Historic Site. A one-hour return tow of the CONSTELLATION is scheduled for Sunday, August 10, 2008. Departure from the Locust Point Cruise Ship Terminal will occur at 7 a.m. and arrival at Pier 1 Inner Harbor at 8 a.m. For both tows, the historic Sloop-of-War USS CONSTELLATION will be towed ''dead ship,'' which means that the vessel will be underway without the benefit of mechanical or sail propulsion. While berthed at the Locust Point Cruise Ship Terminal, the vessel will participate in the commissioning ceremonies for the U.S. Navy's new Arleigh Burke class Aegis guided missile destroyer USS STERETT, DDG 104. The Coast Guard anticipates a large recreational boating fleet during these events, scheduled on a weekend during the summer in Baltimore, Maryland. Operators should expect significant vessel congestion along the planned route.

The purpose of this rule is to promote maritime safety and protect participants and the boating public in the Port of Baltimore immediately prior to, during, and after the scheduled event. The rule will provide for a clear transit route for the participating vessels, and provide a safety buffer around the participating vessels while they are in transit. The rule will impact the movement of all vessels operating upon certain waters of the Patapsco River, Northwest Harbor and Inner Harbor.

Discussion of Comments and Changes

The Coast Guard received no comments in response to the NPRM. No public meeting was requested and none was held. A problem with the number of the rule (.08 versus .05) was discovered and corrected.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. There is little vessel traffic associated with recreational boating and commercial fishing in the area during the effective period.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to operate, remain or anchor within certain waters of the Patapsco River, Northwest Harbor and Inner Harbor, in Baltimore, Maryland, from 5 p.m. through 11 p.m. on August 8, 2008 and from 6 a.m. through 11 a.m. on August 10, 2008. Because the zone is of limited size and duration, it is expected that there will be minimal disruption to the maritime community. Before the effective period, the Coast Guard will issue maritime advisories widely available to users of the river and harbors to allow mariners to make alternative plans for transiting the affected areas. In addition, smaller vessels not constrained by their draft, which are more likely to be small entities, may transit around the safety zone.

Assistance for Small Entities

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

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

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded, under the Instruction, that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g.), of the Instruction, from further environmental documentation. This rule establishes a safety zone.

A final environmental analysis checklist and a final categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, and Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T05–019 to read as follows:

§ 165.T05–019 Safety Zone; Patapsco River, Northwest and Inner Harbors, Baltimore, MD.

(a) Definitions. For the purposes of this section:

(1) *Captain of the Port Baltimore, Maryland* means the Commander, Coast Guard Sector Baltimore or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Baltimore, Maryland to act on his or her behalf.

(2) *USS CONSTELLATION ''turn-around'' participants* means the USS CONSTELLATION, its support craft and the accompanying towing vessels.

(b) Location. The following area is a moving safety zone: all waters within 200 yards ahead of, 100 yards outboard and 100 yards aft of the historic Sloop-of-War USS CONSTELLATION, surface to bottom, while operating in the Inner Harbor, the Northwest Harbor and the Patapsco River.

(c) Regulations:

(1) The general regulations governing safety zones, found in Sec. 165.23, apply to the safety zone described in paragraph (b) of this section.

(2) With the exception of USS CONSTELLATION ''turn-around'' participants, entry into or remaining in this zone is prohibited, unless authorized by the Captain of the Port Baltimore, Maryland.

(3) Persons or vessels requiring entry into or passage through the moving safety zone must first request authorization from the Captain of the Port Baltimore, Maryland to seek permission to transit the area. The Captain of the Port Baltimore, Maryland can be contacted at telephone number (410) 576–2693. The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio VHF Channel 16 (156.8 MHz). Upon being

hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the person or vessel shall proceed as directed. If permission is granted, all persons or vessels must comply with the instructions of the Captain of the Port, Baltimore, Maryland, and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(d) Enforcement. The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State and local agencies.

(e) Effective periods. This section will be effective from 5 p.m. on August 8, 2008 and through 11 a.m. on August 10, 2008.

Dated: June 12, 2008.

Brian D. Kelley,

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

[FR Doc. E8–14601 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0490]

RIN 1625–AA00

Safety Zone; Erie Summer Festival of the Arts, Presque Isle Bay, Erie, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Lake Erie, Presque Isle Bay, Erie, PA. This zone is intended to restrict vessels from a portion of Presque Isle Bay during the June 28, 2008, Erie Summer Festival of the Arts fireworks event. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with fireworks displays.

DATES: This rule is effective from 10 p.m. to 11 p.m. on June 28, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0490 and are available for inspection or copying at two locations: the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the U.S. Coast Guard Sector Buffalo, 1 Fuhrmann Boulevard, Buffalo, NY 14203 between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Commander Joseph Boudrow, Prevention Division, U.S. Coast Guard Sector Buffalo, at 716–843–9572. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The permit application was not received in time to publish an NPRM followed by a final rule before the effective date. Under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective fewer than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property.

Background and Purpose

This temporary safety zone is necessary to ensure the safety of vessels and spectators from hazards associated with a fireworks display. Based on accidents that have occurred in other Captain of the Port zones, and the explosive hazards of fireworks, the Captain of the Port Buffalo has determined that fireworks launches proximate to watercraft pose a significant risk to public safety and property. The likely combination of large numbers of recreation vessels, congested waterways, darkness punctuated by bright flashes of light, alcohol use, and debris falling into the water could easily result in serious injuries or fatalities. Establishing a safety zone to control vessel movement around the location of the launch platform will help ensure the safety of persons and property at these events and help minimize the associated risks.

Discussion of Rule

A temporary safety zone is necessary to ensure the safety of spectators and vessels during the setup, loading and launching of a fireworks display in conjunction with the Erie Summer festival of the Arts fireworks display. The fireworks display will occur between 10 p.m. and 11 p.m. on June 28, 2008.

The safety zone for the fireworks will encompass all waters of Lake Erie, Presque Isle Bay, Erie, PA, within a 420 ft radius of position 42°07′45″ N, 080°06′20″ W.

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the on-scene representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his on-scene representative. The Captain of the Port or his on-scene representative may be contacted via VHF Channel 16.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

This determination is based on the minimal time that vessels will be restricted from the zone and the zone is an area where the Coast Guard expects insignificant adverse impact to mariners from the zones' activation.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to transit or anchor in a portion of Lake Erie, Presque Isle Bay, Erie, PA, between 10 p.m. and 11 p.m. on June 28, 2008.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will be in effect for only one hour for one event. Vessel traffic can safely pass outside the safety zone during the event. In the event that this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of the Port Buffalo to transit through the safety zone. The Coast

Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate tribal concerns. We have determined that these regulations and fishing rights protection need not be incompatible. We have also determined that this Rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Nevertheless, Indian Tribes that have questions concerning the provisions of this Rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. This event establishes a safety zone therefore paragraph (34)(g) of the Instruction applies.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, and Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. A new temporary § 165.T09–0490 is added as follows:

§ 165.T09–0490 Safety zone; Erie Summer Festival of the Arts, Lake Erie, Presque Isle Bay, Erie, PA.

(a) *Location.* The following area is a temporary safety zone: all waters of Lake Erie, Presque Isle Bay, Erie, PA, within a 420 ft radius of position (42°07′45″ N, 080°06′20″ W). (DATUM: NAD 83).

(b) *Effective period.* This regulation is effective from 10 p.m. to 11 p.m. on June 28, 2008.

(c) *Regulations.*

(1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo, or his on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo or his on-scene representative.

Dated: *June 13, 2008.*

S.J. Ferguson,

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

[FR Doc. E8–14615 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0569]

RIN 1625–AA87

Security Zone; Waters Adjacent 10th Avenue Marine Terminal, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone in the waters adjacent to the 10th Avenue Marine Terminal, San Diego Bay, San Diego, CA. This action is needed to protect the U.S. Naval vessels, their crews and the public during a military out load evolution from sabotage or other subversive acts, accidents, criminal actions or other causes of a similar nature. Entry, transit or anchoring in this zone is prohibited unless authorized by the Captain of the Port San Diego, or his designated representative.

DATES: This rule is effective from 7 a.m. on June 25, 2008, to 7 p.m. on June 28, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of Docket No. 2008–0569 and are available for inspection or copying at Coast Guard Sector San Diego, 2710 N. Harbor Drive, San Diego, CA 92101–1064 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chief Petty Officer Eric Carroll, Waterways Management, Coast Guard Sector San Diego, at telephone (619) 278–7268.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Based on the military function exception set forth in the Administrative Procedure Act, 5 U.S.C. 553(a)(1), notice-and-comment rulemaking and advance publication, pursuant to 5 U.S.C. 553(b) and (d), are not required for this regulation. In addition, even if an NPRM were otherwise required, under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Under 5 U.S.C. 553(d)(3), the Coast Guard also finds that good cause exists for making this regulation effective less than 30 days after publication in the **Federal Register**. It would be contrary to public interest to delay the effective date of this temporary rule.

Background and Purpose

The U.S. Military Surface Deployment and Distribution Command notified the Coast Guard concerning military out load operations at the Port of San Diego's Tenth Avenue Marine Terminal for the dates given. This temporary security zone is needed to protect the U.S. Naval vessels and their crews for the duration of the evolution of military out load operations.

Discussion of Rule

The security zone generally consists of the navigable waters surrounding the 10th Avenue Marine Terminal. The limits of this security zone are more specifically defined as the area enclosed by the following points: starting on shore at 32°42′15″ N 117°09′39″ W, then extending southwesterly to 32°42′02″ N 117°09′51″ W, then southeasterly to 32°41′43″ N 117°09′25″ W, northeasterly to shore at 32°41′47″ N 117°09′20″ W and then along the shoreline to starting point.

The security zone will be enforced by Coast Guard patrol craft and San Diego Harbor Police as authorized by the Captain of the Port San Diego (COTP). See 33 CFR 6.04–11, Assistance of other agencies. Persons and vessels are prohibited from entering into or transiting through this security zone unless authorized by the Captain of the Port, or his designated representative.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Due to National Security interests, the implementation of this security zone is necessary for the protection of the United States and its people. The size of the zone is the minimum necessary to provide adequate protection for the U.S. Naval vessels, their crews, adjoining areas and the public. Most of the entities likely to be affected are pleasure craft engaged in recreational activities and sightseeing. Any hardships experienced by persons or vessels are considered minimal compared to the national interest in protecting U.S. Naval vessels, their crews and the public.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to transit or anchor in the portion of San Diego Bay south of Harbor Island from 7 a.m. on June 25, 2008, to 7 p.m. on June 28, 2008. However, these security zones will not have a significant economic impact on a substantial number of small entities because these zones are limited in scope and duration. In addition, the Coast Guard will issue broadcast notice to mariners (BNM) alerts via VHF-FM marine channel 16 before the security zone is enforced.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If your small business or organization is affected by this rule and you have questions concerning its provisions or options for compliance, please contact Chief Petty Officer Eric Carroll, Waterways Management, Sector San Diego at (619) 278–7268.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because we are establishing a security zone.

A final ''Environmental Analysis Checklist'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Section 165.T11–063 is added to read as follows:

Section 165.T11–063 Security Zone; Waters Adjacent 10th Avenue Marine Terminal, San Diego, CA

(a) *Location*. The security zone consists of the navigable waters surrounding the 10th Avenue Marine Terminal. The limits of this security zone are more specifically defined as the area enclosed by the following points: Starting on shore at 32°42′15″ N 117°09′39″ W, then extending southwesterly to 32°42′02″ N 117°09′51″ W, then southeasterly to 32°41′43″ N 117°09′25″ W, northeasterly to shore at 32°41′47″ N 117°09′20″ W and then along the shoreline to starting point.

(b) *Effective period*. This section will be in effect from 7 a.m. on June 25, 2008, to 7 p.m. on June 28, 2008. If the need for the security zone ends before the scheduled termination time, the Captain of the Port San Diego will cease enforcement of this security zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations*. In accordance with the general regulations in § 165.33 of this part, entry into, transit through, or anchoring within the security zone described in paragraph (a) of this section by all vessels is prohibited, unless authorized by the Captain of the Port, or his designated representative. All other general regulations of § 165.33 of this part apply in the security zone established by this section.

(d) *Enforcement*. All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene patrol personnel. Patrol personnel can be comprised of commissioned, warrant, and petty officers of the Coast Guard onboard Coast Guard, local, state, and federal law enforcement vessels. Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. The U.S. Coast Guard may be assisted in the patrol and enforcement of this security zone by the San Diego Harbor Police.

Dated: June 18, 2008.

C.V. Strangfeld,

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

[FR Doc. E8–14613 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0146]

RIN 1625–AA00

Temporary Safety Zone; Wreckage of the M/V NEW CARISSA, Pacific Ocean 3 Nautical Miles North of the Entrance to Coos Bay, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary Final Rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Pacific Ocean encompassed in the 1000 yard radius surrounding the wreckage of the M/V NEW CARISSA located 3 NM north of the entrance to Coos Bay, Oregon. The Captain of the Port Portland is taking this action to safeguard individuals and vessels involved in a salvage operation involving the M/V NEW CARISSA. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his designated representative.

DATES: This regulation is effective from 10 a.m. June 5, 2008, to 11:59 p.m. August 31, 2008, unless canceled earlier through broadcast notice to mariners.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0146 and are available online at *http://www.regulations.gov*. They are also available for inspection or copying at two locations: the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and Coast Guard Sector Portland, 6767 N. Basin Ave., Portland, OR 97217 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: MST1 Lucia Mack, Waterways Management, c/o Captain of the Port Portland, 6767 N. Basin Ave, Portland, OR 97217–3992, and (503) 240–9311.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard was not given a start date for this operation and just recently became aware of its progress which did not allow for prior notice. Publishing a NPRM would be contrary to public interest since immediate action is necessary to allow for the safe salvage of the wreckage of the M/V NEW CARISSA which is aground upon a sand bar in the Pacific Ocean 3 NM north of the entrance to Coos Bay, Oregon. If normal notice and comment procedures were followed, this rule would not become effective until after the date of the salvage operation. For this reason, following the normal rulemaking procedures in this case would be impracticable and contrary to the public safety.

Background and Purpose

The Coast Guard is establishing a temporary safety zone on the waters of the Pacific Ocean encompassed in the 1000 yard radius surrounding the wreckage of the M/V NEW CARISSA located 3 NM north of the entrance to Coos Bay, Oregon. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his designated representative from 10 a.m. June 5, 2008, to 11:59 p.m. August 31, 2008, unless canceled earlier through broadcast notice to mariners.

The Captain of the Port Portland is taking this action to safeguard individuals and vessels involved in a salvage operation involving the wreck of the M/V NEW CARISSA. This safety zone will be enforced by representatives of the Captain of the Port Portland. The Captain of the Port may be assisted by other federal, state, and local agencies.

Discussion of Rule

This rule, for safety concerns, will control vessels, personnel, and individual movements on the waters of the Pacific Ocean encompassed in the 1000 yard radius surrounding the wreckage of the M/V NEW CARISSA located 3 NM north of the entrance to Coos Bay, Oregon as indicated in section 2 of this Temporary Final Rule. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his designated representative. Coast Guard Personnel and local law enforcement will enforce this safety zone. The Captain of the Port may be assisted by other federal and local agencies.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not

require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. The Coast Guard expects the economic impact of this proposal to be so minimal the full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures unnecessary. This expectation is based on the fact that the regulated areas established by the proposed regulation will involve a small area of the Pacific Ocean along the Oregon Coast that doesn't have much vessel traffic. The removal of the wreckage of the M/V NEW CARISSA in a controlled and deliberate operation ensures the safety of future traffic in that the vessel will not be allowed to deteriorate in a fashion which could cause unknown navigation hazards and/or additional pollution in the area. The removal of the wreck's potential to create these incidents will offset any potential adverse economic impact these restrictions might have.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit a small area of the Pacific Ocean along the Oregon Coast encompassed in the 1000 yard radius surrounding the wreckage of the M/V NEW CARISSA located 3 NM north of the entrance to Coos Bay, Oregon. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his designated representative. This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: The safety zone applies to a tiny portion of the Pacific Ocean, entities wishing to transit in the vicinity of this area may pass outside of the safety zone to continue their transit. We will issue a broadcast notice to mariners on the effected portion of the Pacific Ocean.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they may better evaluate its effects on them and participate in the rulemaking process. If this rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded, under the Instruction, that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because it establishes a safety zone.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and Record Keeping Requirements, Security Measures, and Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. A temporary section in 165.T13–035 is added to read as follows:

§ 165.T13–035 Safety Zone: Wreckage of the M/V NEW CARISSA, Pacific Ocean 3 Nautical Miles North of the Entrance to Coos Bay, Oregon.

(a) Location. The following area is a safety zone: The waters of the Pacific Ocean encompassed by a 1000 yard radius surrounding the wreckage of the M/V NEW CARISSA located 3 NM north of the entrance to Coos Bay, Oregon.

(b) Enforcement period. This rule will be in effect from 10 a.m. June 05, 2008, to 11:59 p.m. August 31, 2008.

(c) Regulations. In accordance with the general regulations in § 165.23 of this part, entry into this safety zone is prohibited unless authorized by the Captain of the Port or his designated representative.

Dated: June 5, 2008.

F.G. Myer,

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

[FR Doc. E8–14616 Filed 6–26–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2006–0130–200814; FRL–8684–4]

Approval and Promulgation of Implementation Plans Florida; Prevention of Significant Deterioration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to conditionally approve revisions to the Florida State Implementation Plan (SIP) submitted by the State of Florida on February 3, 2006. The SIP revisions modify the Florida Prevention of Significant Deterioration (PSD) program to address changes to the federal new source review (NSR) regulations, which were promulgated by EPA on December 31, 2002, and reconsidered with minor changes on November 7, 2003 (commonly referred to as the ''2002 NSR Reform Rules''). In addition EPA is approving Florida's concurrent February 3, 2006, request to make the State's PSD permitting program applicable to electric power plants, which are also subject to the Florida Electrical Power Plant Siting Act (PPSA). EPA proposed conditional approval of these revisions on April 4, 2008; no comments were received on that proposal.

DATES: *Effective Date:* This rule will be effective July 28, 2008.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2006–0130. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Regulatory Development 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 if at all possible, 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.

FOR FURTHER INFORMATION CONTACT: For information regarding the Florida State Implementation Plan, contact Ms. Heidi LeSane, Regulatory Development 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) 562–9074. Ms. LeSane can also be reached via electronic mail at *lesane.heidi@epa.gov.* For information regarding New Source Review, contact Ms. Yolanda Adams, Air Permits Section, at the same address above. The telephone number is (404) 562–9214. Ms. Adams can also be reached via electronic mail at *adams.yolanda@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. What action is EPA taking?

NSR Reform Revisions. EPA is taking final action to conditionally approve revisions to the Florida SIP (Florida Administrative Code (F.A.C.) Chapters 62–204, 62–210, and 62–212) as submitted by the Florida Department of Environmental Protection (FDEP) on February 3, 2006, which included changes to Florida's PSD program. As part of the current conditional approval, Florida has agreed to (1) revise the definition of ''new emissions unit'' to be consistent with the federal definition or revise the definition to define what is meant by ''beginning normal operation'' and provide an equivalency demonstration supporting the revised definition; (2) revise the definition of ''significant emissions rate'' to include ozone depleting substances; (3)

withdraw the request that EPA include a significant emissions rate for mercury in the Florida SIP, specifically F.A.C. Chapter 62–210.200(243)(a)2; and (4) revise the recordkeeping requirements at F.A.C. section 62–212.300(3)(a)1 to be consistent with federal requirements found at 40 CFR 51.166(r)(6).

Applicability of Florida's SIP-approved PSD permitting program to electric power plants. In addition to and in conjunction with the conditional approval of Florida's PSD SIP revisions, EPA is approving Florida's concurrent February 3, 2006, request to make the State's PSD permitting program applicable to electric power plants subject to the Florida PPSA. This means that Florida's SIP-approved PSD permitting program, including the conditional approval of the State's PSD revisions noted above, will apply to electric power plants in Florida in lieu of the current federally delegated PSD program.

On April 4, 2008 (73 FR 18466), EPA published a notice of proposed rulemaking (NPR) in the **Federal Register**, proposing to conditionally approve the Florida SIP revisions and proposing to approve Florida's request to make the State's PSD program applicable to electric power plants, which are also subject to the Florida PPSA. The April 4, 2008, NPR provides additional information about the proposed Florida SIP revisions and the rationale for this final action. The public comment period for the proposed action ended on May 5, 2008. No comments were received on EPA's proposed action. EPA is now taking final action to conditionally approve the February 3, 2006, SIP revision from Florida and to approve Florida's request to make the State's PSD permitting program applicable to electric power plants subject to the Florida PPSA.

II. What is the background of EPA's action on the Florida PSD rule revisions?

On December 31, 2002 (67 FR 80186), EPA published final rule changes to 40 Code of Federal Regulations (CFR) parts 51 and 52, regarding the Clean Air Act (''CAA'' or ''Act'') PSD and nonattainment new source review (NNSR) programs. On November 7, 2003 (68 FR 63021), EPA published a notice of final action on its reconsideration of the December 31, 2002, final rule changes. In that November 7, 2003, final action, EPA added the definition of ''replacement unit,'' and clarified an issue regarding plant-wide applicability limitations. Collectively, these EPA final actions are referred to as the ''2002 NSR Reform Rules.'' On June 13, 2007 (72 FR 32526), EPA took final action to revise the 2002 NSR Reform Rules to exclude the clean units and PCP provisions that were vacated by the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit Court) on June 24, 2005. Further, on December 21, 2007, EPA took final action on the portion of the 2002 NSR Reform Rules remanded by the D.C. Circuit Court, regarding the reasonable possibility in recordkeeping provision. The ''reasonable possibility'' provision identifies, for sources and reviewing authorities, the circumstances under which a major stationary source undergoing a modification that does not trigger major NSR must keep records. On December 21, 2007, EPA established that a ''reasonable possibility'' exists where source emissions equal or exceed 50 percent of the CAA NSR significance levels for any pollutant (72 FR 72607). These changes became effective on January 22, 2008, and the final action on that provision explains the process that states should follow if a SIP revision is necessary.[1]

The Florida SIP revisions being approved today revise Florida's PSD program consistent with the federal program. In so doing, Florida not only provided substantive revisions to its rules, but also reorganized the rules to better follow the outline of the corresponding federal rules. This reorganization does not have any substantive impact on the PSD program as a whole, or its relationship with Florida's operating permits program (CAA title V program). Florida's PSD program continues to work in concert with its title V operating permit program to ensure that applicable requirements, including any applicable PSD requirements, are a part of lawful operation of a source under Florida's title V program.

The February 3, 2006, SIP submittal consists of revisions to the following FDEP rules: F.A.C. Chapter 62–204, ''Air Pollution Control—General Provisions;'' F.A.C. Chapter 62–210, ''Stationary Sources—General Provisions;'' and F.A.C. Chapter 62–212, ''Stationary Sources—Preconstruction Review.'' The revisions were made to update the Florida PSD program to make it consistent with the December 31, 2002, changes to the federal NSR program. EPA is conditionally approving the February 3, 2006, SIP submittal consistent with section 110(k)(4) of the CAA. As part of the conditional approval, Florida will have twelve months from the date of EPA's final conditional approval of the SIP revisions in which to further revise its PSD rules, as described herein, to be consistent with existing federal law.

Pursuant to section 110(k)(4) of the CAA, EPA may conditionally approve a portion of a SIP revision based on a commitment from the state to adopt specific, enforceable measures no later than twelve months from the date of final conditional approval. If the state fails to make the changes within the twelve month period, EPA will issue a finding of disapproval. EPA is not required to propose the finding of disapproval. The necessary revisions to the Florida SIP will materially alter the existing SIP-approved rule. As a result, Florida must also provide a new SIP submittal to EPA for approval that includes the rule changes. As with any SIP revision, Florida must provide an opportunity for public notice and comment, and allow for a public hearing (and any other procedures required by State law) on the proposed rule changes. If Florida timely revises its rules and submits the revised SIP submittal, EPA will process that SIP revision consistent with the CAA.

With regard to the conditional approval of the PSD program, Florida must: (1) Revise the definition of ''new emissions unit'' to be consistent with the federal definition or revise the definition to define what is meant by ''beginning normal operation'' and provide an equivalency demonstration supporting the revised definition; (2) revise the definition of ''significant emissions rate'' to include ozone depleting substances; (3) withdraw the request that EPA include a significant emissions rate for mercury in the Florida SIP, specifically F.A.C. 62–210.200(243)(a)2; and (4) revise the recordkeeping requirements at F.A.C. 62–212.300(3)(a)1 to require a record of the amount of emissions excluded pursuant to the projected actual emissions requirements, an explanation as to why these emissions were excluded, and any netting calculations if applicable, consistent with the federal recordkeeping requirements at 40 CFR 51.166(r)(6).

The April 4, 2008, NPR and the docket for this action provide more details about the SIP revisions being approved and the rationale for EPA's final action. For additional information on EPA's 2002 NSR Reform Rules, see 67 FR 80186 (December 31, 2002), and *http://www.epa.gov/nsr.*

[1] Florida's regulations do not include the ''reasonable possibility'' language. Florida's SIP revisions require all modifications that use the actual-to-projected-actual methodology to meet the recordkeeping requirements. Thus, with regard to the reasonable possibility issue, Florida's rules are at least as stringent as the current federal rules.

III. What is the background of EPA's action on Florida's PSD program for electric power plants?

Electric power plants subject to the Florida PPSA have historically been permitted by FDEP (through a federal delegation of authority from EPA) under the federal PSD program rather than the Florida SIP-approved PSD permitting program. The Florida PSD program was initially approved by EPA into the Florida SIP on December 22, 1983 (48 FR 52713). The approval transferred to FDEP the legal authority to process and issue PSD permits to sources in Florida that are required to obtain PSD permits.

One category of sources not covered by EPA's 1983 approval of Florida's PSD program was electric power plants. This was because, at the time, a separate Florida law known as the Florida PPSA, Florida Statutes Section 403.501 *et seq.*, required permits for electric power plants to be issued solely by the Power Plant Site Certification Board under the PPSA, rather than by FDEP under Florida's PSD regulations. Such a conflict between the PPSA and Florida's PSD program created impediments to implementation and enforcement of the State's PSD program by FDEP for such power plants and precluded EPA's SIP-approval of Florida's PSD program as to these sources. As a result, for electric power plants subject to the PPSA, FDEP has been operating under either a partial or full delegation of authority to implement the federal PSD program since 1983, while various attempts to amend the PPSA to correct the conflict were made. Currently, FDEP is operating under a full delegation of authority to implement the federal PSD program for electric power plants, following further amendments to the PPSA in 1993. The 1993 PPSA amendment made clear that FDEP is the final permitting authority for PSD and new source review permits and can act in a manner different from the PPSA Siting Board if Florida's PSD or new source review regulations require such different action. The statutory amendment to the PPSA made by the Florida Legislature in 1993 forms the basis of the State's 2006 request for EPA approval to make Florida's SIP-approved State PSD program, rather than the federal PSD program, applicable to sources subject to the PPSA. In addition, during EPA's review of this request, the PPSA was again amended (on June 19, 2006), to among other things, further extricate Florida's PSD permitting process from its PPSA process. See, Florida Public Health Code 403.0872.

Following EPA review of both the 1993 and June 19, 2006, amendments to the PPSA, the Agency published a direct final rule on May 25, 2007, finding that the PPSA amendments provided FDEP the authority to fully implement and enforce Florida's PSD program for electric power plants located within the State, and we granted it full approval to implement the State's PSD program for electric power plants subject to the PPSA. 72 FR 29287 (May 25, 2007). However, because adverse comments on the direct final rule were received, EPA withdrew the rule on June 28, 2007 (72 FR 35355) and indicated that the rule would not take effect.

As is described in greater detail in the April 4, 2008, proposal, the 1993 and June 2006 Florida legislative amendments to the State's PPSA rectified past concerns that the Florida PPSA infringed on FDEP's authority to issue State PSD permits to sources subject to both the State's PSD regulations and the Florida PPSA in such a manner that SIP-approval of the State's PSD program for those sources was precluded. By proposing this SIP-approval through this new rulemaking process, and in conjunction with our proposed action on the Florida PSD program SIP revisions, we have addressed the main concerns raised by commenters in response to our May 25, 2007, direct final rule. For additional information on the concerns raised by commenters, see the April 4, 2008, proposal.

EPA is now approving Florida's February 3, 2006, request that EPA grant Florida SIP-approval to implement the State's PSD program for electric power plants subject to the PPSA. EPA is approving this specific request under section 110 of the Act because there is no longer a conflict between the State's PSD regulations and the PPSA and because FDEP now has adequate and effective procedures for full implementation of the State's PSD program for electric power plants. The April 4, 2008, NPR and the docket for this action provide more details about the approval of Florida's PSD program for electric power plants and the rationale for EPA's final action.

IV. Final Action

EPA is taking final action to conditionally approve changes to the Florida Administrative Code Chapter 62–204 entitled ''Air Pollution Control—General Provisions''; Chapter 62–210 entitled ''Stationary Sources—General Provisions''; and Chapter 62–212 entitled ''Stationary Sources—Preconstruction Review,'' as submitted by the State of Florida on February 3, 2006, as revisions to the Florida SIP.

In addition to and in conjunction with the conditional approval of Florida's PSD SIP revisions, EPA is taking final action to approve Florida's concurrent February 3, 2006, request to make the State's PSD permitting program applicable to electric power plants subject to the Florida PPSA. As a result of this final action, EPA's October 26, 1993, federal delegation of PSD authority to FDEP will be withdrawn effective July 28, 2008. This final approval means that Florida's SIP-approved PSD permitting program, including the final conditional approval of the State's PSD revisions noted above, applies to electric power plants in Florida in lieu of the current federally delegated PSD program.

V. Statutory and Executive Order Reviews

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

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

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 26, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: June 16, 2008.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart K—Florida

■ 2. Section 52.519 is revised 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 revisions to Florida Administrative Code Chapters 62–210 and 62–212. Based upon a commitment from the State, Florida must (1) revise the definition of ''new emissions unit'' to be consistent with the federal definition or revise the definition to define what is meant by ''beginning normal operation'' and provide an equivalency demonstration supporting the revised definition; (2) revise the definition of ''significant emissions rate'' to include ozone depleting substances; (3) withdraw the request that EPA include a significant emissions rate for mercury in the Florida SIP, specifically F.A.C. 62–210.200(243)(a)2; and (4) revise the recordkeeping requirements at F.A.C. 62–212.300 to be consistent with federal requirements. If the State fails to meet its commitment by June 29, 2009, the approval is treated as a disapproval.

■ 3. Section 52.520(c) is amended by:

■ a. Revising entries under Chapter 62–204 for ''62–204.200,'' and ''62–204.260,'' under Chapter 62–210 for ''62–210.200,'' ''62–210.300,'' ''62–210.350''and ''62–210.370,'' under Chapter 62–212 for ''62–212.300,'' ''62–212.400,'' and ''62–212.500'' and

■ b. Adding in numerical order a new entry under Chapter 62–212 for ''62–212.720'' to read as follows:

§ 52.520 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED FLORIDA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
Chapter 62–204 Air Pollution Control—General Provisions				
*	*	*	*	*
62–204.200	Definitions	02/12/06	06/27/08 [Insert citation of publication].	
*	*	*	*	*
62–204.260	Prevention of Significant Deterioration Maximum Allowable Increases (PSD Increments).	02/12/06	06/27/08 [Insert citation of publication].	
*	*	*	*	*
Chapter 62–210 Stationary Sources—General Requirements				
*	*	*	*	*
62–210.200	Definitions	02/02/06	06/27/08 [Insert citation of publication].	Except for the following definitions which are being conditionally approved: (1) ''New emissions unit;'' and (2) ''significant emissions rate.''

EPA-APPROVED FLORIDA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
62–210.300	Permits Required	02/02/06	06/27/08 [Insert citation of publication].	
62–210.350	Public Notice and Comment	02/02/06	06/27/08 [Insert citation of publication].	
*	*	*	*	*
62–210.370	Emissions Computation and Reporting.	02/02/06	06/27/08 [Insert citation of publication].	
*	*	*	*	*
Chapter 62–212 Stationary Sources—Preconstruction Review				
*	*	*	*	*
62–212.300	General Preconstruction Review Requirements.	02/02/06	06/27/08 [Insert citation of publication].	Except provisions at 62–212.300(3)(a)1, which are being conditionally approved.
62–212.400	Prevention of Significant Deterioration (PSD).	02/02/06	06/27/08 [Insert citation of publication].	
62–212.500	Preconstruction Review for Nonattainment Areas.	02/02/06	06/27/08 [Insert citation of publication].	
*	*	*	*	*
62–212.720	Actuals Plantwide Applicability Limits (PALs).	02/02/06	06/27/08 [Insert citation of publication].	

* * * * *

■ 4. Section 52.530 is amended by revising paragraph (a) to read as follows:

§ 52.530 Significant deterioration of air quality.

(a) EPA approves the Florida Prevention of Significant Deterioration program, as incorporated into this chapter, for power plants subject to the Florida Power Plant Siting Act.

* * * * *

[FR Doc. E8–14400 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2007–0998; FRL–8684–1]

Approval and Promulgation of State Implementation Plans: Washington; Vancouver Air Quality Maintenance Area Second 10-Year Carbon Monoxide Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a State Implementation Plan (SIP) revision submitted by the State of Washington. The Washington State Department of Ecology submitted the Vancouver Air Quality Maintenance Area Second 10-year Carbon Monoxide Maintenance Plan on April 25, 2007. In accordance with the requirements of the Federal Clean Air Act (the Act), EPA is approving Washington's revision because the State adequately demonstrates that the Vancouver Air Quality Maintenance Area will maintain air quality standards for carbon monoxide (CO) through the year 2016.

DATES: This rule is effective on August 26, 2008, without further notice, unless EPA receives adverse comment by July 28, 2008. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2007–0998, by any of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: vaupel.claudia@epa.gov.*
- *Mail:* Claudia Vergnani Vaupel, U.S. EPA Region 10, Office of Air, Waste and Toxics (AWT–107), 1200 Sixth Avenue, Suite 900, Seattle, WA 98101.
- Hand Delivery/Courier: U.S. EPA Region 10, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. Attention: Claudia Vergnani Vaupel, Office of Air, Waste and Toxics, AWT—107. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R10–OAR–2007–0998. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in

the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Office of Air, Waste and Toxics, U.S. EPA Region 10, 1200 Sixth Avenue, Seattle, WA 98101.

FOR FURTHER INFORMATION CONTACT: Claudia Vergnani Vaupel at telephone number: (206) 553–6121, e-mail address: *vaupel.claudia@epa.gov*, fax number: (206) 553–0110, or Gina Bonifacino at telephone number: (206) 553–2970, e-mail address: *bonifacino.gina@epa.gov*, or the above EPA, Region 10 address.

SUPPLEMENTARY INFORMATION:

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I. General Information

A. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through RME, regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

2. Tips for Preparing Your Comments. When submitting comments, remember to:

i. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What Is the Purpose of This Action?

EPA is taking direct final action to approve the Second 10-year CO Maintenance Plan for the Vancouver, Washington Air Quality Maintenance Area. Vancouver attained the CO national ambient air quality standards (NAAQS) in 1996 and has not violated the standard since 1990. The second 10-year CO maintenance plan submitted by the state of Washington is designed to keep the Vancouver area in attainment for the CO standard for a second ten-year period beyond redesignation.

III. What Is the Background for This Action?

Under section 107(d)(1)(C) of the Act, any area designated before the date of enactment of the Clean Air Act Amendments of 1990 (CAAA) was to be designated upon enactment by operation of law. Under section 107(d)(1)(A) of the Act, States were required by 120 days after enactment of the CAAA, to submit lists designating all areas of the State as attainment, unclassifiable, or nonattainment.

Accordingly, on March 15, 1991, letters were submitted by the governors of Washington and Oregon to the EPA Region 10 Administrator recommending the Vancouver and Portland areas, respectively, be designated as nonattainment for CO. On November 6, 1991 (56 FR 56694) the areas were designated by EPA as nonattainment for CO and classified as ''moderate'' with design values less than or equal to 12.7 parts per million (ppm) under the provisions outlined in sections 186 and 187 of the Act. On September 29, 1995 (60 FR 50423) EPA divided the Portland-Vancouver area into separate nonattainment areas for each state.

The State of Washington, following the requirements of the Act, prepared and submitted revisions to the Washington SIP that first included an attainment plan, and then developed a plan to demonstrate maintenance of the standard for a 10-year period beyond the statutory attainment date. EPA published approval of a redesignation request to attainment and the first 10-year maintenance plan on October 21, 1996 (61 FR 54560). The first 10-year CO maintenance plan included a commitment for periodic review of the plan and submission of the second 10-year maintenance plan. The State of Washington submitted a second 10-year maintenance plan to EPA on April 25, 2007.

The national 8-hour CO ambient standard is attained when the daily average 8-hour CO concentration of 9.0 ppm is not exceeded more than once a year. Since the redesignation of the Vancouver area to attainment for CO on October 21, 1996, the second highest concentration in any calendar year measured by the approved monitoring network was 6.7 ppm, which is less than 9.0 ppm. Therefore the area is attaining the CO NAAQS.

In addition, areas that can demonstrate design values at or below 7.65 ppm (85 percent of exceedance levels of the CO NAAQS) for 8 consecutive quarters may use a Limited Maintenance Plan option. The current 8-hour CO design value for the Vancouver area is 4.8 ppm based on 2004–2005 data. The State of Washington has opted to develop a Limited Maintenance Plan to fulfill the Vancouver Area second 10-year maintenance period required by the Act.

IV. How Have the Public and Stakeholders Been Involved in This Rulemaking Process?

Section 110(a)(2) of the Act requires that each SIP revision be adopted after reasonable notice and public hearing. This must occur prior to the revision being submitted by a State to us. The state of Washington held a public hearing on March 1, 2007 in Vancouver, Washington. A notice of public hearing

was published in *The Columbian* on January 29, 2007. A notice was also published in the Washington State Register on February 7, 2007. This SIP revision became State effective on April 9, 2007, and was submitted by the Governor's designee to us on April 25, 2007. EPA has evaluated the State's submittal and determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2) of the Act.

V. Evaluation of Washington's Submittal

EPA has reviewed the State's revised CO maintenance plan for the Vancouver air quality maintenance. This revision provides the second 10-year update to the maintenance plan for the area, as required by section 175A(b) of the Act. The following is a summary of the requirements and EPA's evaluation of how each requirement is met.

A. Base Year Emissions Inventory

The plan must contain an attainment year emissions inventory to identify a level of emissions in the area which is sufficient to attain the CO NAAQS. The Vancouver CO second 10-year maintenance plan contains an emissions inventory for the base year 2002 that is consistent with EPA's most recent guidance on maintenance plan emission inventories. The emissions inventory is a list, by source, of the air contaminants directly emitted into the Vancouver CO area. The data in the emissions inventory is based on calculations and is developed using emission factors, which is a method for converting source activity levels into an estimate of emissions contributions for those sources. Because violations of the CO NAAQS are most like to occur on winter weekdays, the inventory prepared is in a ''typical winter day'' format. The table below shows the pounds of CO emitted per winter day in 2002 by source category.

2002 EMISSION INVENTORY, MAIN SOURCE CATEGORY SUBTOTALS

Main source category	CO emissions pounds per winter day (lb/d)
Point Sources	4,396
Onroad Mobile Sources	383,058
Non-road Mobile Sources	56,837
Area Sources	126,377
Total	570,669

B. Demonstration of Maintenance

The maintenance plan demonstration requirement is considered to be satisfied for areas using the Limited Maintenance Plan option, which are required to demonstrate design values at or below 7.65 ppm (85 percent of exceedance levels of the CO NAAQS) for 8 consecutive quarters. The State of Washington has opted to develop a Limited Maintenance Plan to fulfill the Vancouver Area second 10-year maintenance period required by the Act.

With the Limited Maintenance Plan option, there is no requirement to project emissions of air quality over the maintenance period. EPA believes that if the area begins the maintenance period at, or below, 85 percent of the level of the CO 8-hour NAAQS, the applicability of prevention of significant deterioration requirements, the control measures already in the SIP, and Federal measures, should provide adequate assurance of maintenance over the 10-year maintenance period. The last monitored violation of the CO NAAQS in Vancouver occurred in 1990 and monitored CO levels have been steadily in decline ever since. The current 8-hour CO design value for the Vancouver CO area is 4.8 ppm based on 2004–2005 data, which is below the limited maintenance plan requirement of 7.65 ppm. Therefore, the Vancouver area has adequately demonstrated that it will maintain the CO NAAQS into the future.

C. Monitoring Network and Verification of Continued Attainment

To verify the attainment status of the area over the maintenance period, the maintenance plan should contain provisions for continued operation of an appropriate, EPA-approved monitoring network in accordance with 50 CFR part 58. The State of Washington has an approved monitoring network that includes the Vancouver area. The monitoring network was most recently approved by EPA on November 16, 2007. In 2006, the Southwest Clean Air Agency requested permission to remove the CO monitor at the Atlas and Cox site in Vancouver and EPA concurred that monitoring could be discontinued at the site. The State is continuing to verify attainment by conducting a triennial review of CO emissions from the countywide emissions inventory.

D. Contingency Plan

Section 175A(d) of the Act requires that a maintenance plan include contingency provisions. The Vancouver Area CO Maintenance Plan contains a tiered level of response should the triennial emission inventory show that annual county-wide on road mobile emissions have increased over 2005 levels. The contingency plan calls for analysis of appropriate emission reduction measures and their implementation.

VI. Transportation and General Conformity

Transportation conformity is required by section 176(c) of the Clean Air Act. EPA's conformity rule requires that transportation plans, programs, and projects that are funded under 23 U.S.C. or the Federal Transit Act conform to SIPs. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS.

The transportation conformity rule (40 CFR parts 51 and 93) and the general conformity rule (40 CFR parts 51 and 93) apply to nonattainment areas and maintenance areas covered by an approved maintenance plan. Under either conformity rule, an acceptable method of demonstrating that a Federal action conforms to the applicable SIP is to demonstrate that expected emissions from the planned action are consistent with the emissions budget for the area.

While EPA's Limited Maintenance Plan option does not exempt an area from the need to affirm conformity, it explains that the area may demonstrate conformity without submitting an emissions budget. Under the Limited Maintenance Plan option, emissions budgets are treated as essentially not constraining for the length of the maintenance period because it is unreasonable to expect that the qualifying areas would experience so much growth in that period that a violation of the CO NAAQS would result. Similarly, Federal actions subject to the general conformity rule could be considered to satisfy the ''budget test'' specified in section 93.158(a)(5)(i)(A) for the same reasons that the budgets are essentially considered to be unlimited.

1. Transportation Conformity

While areas with maintenance plans approved under the Limited Maintenance Plan option are not subject to the budget test, the areas remain subject to other transportation conformity requirements of 40 CFR part 93, subpart A. Thus, the metropolitan planning organization (MPO) in the area or the State must document and ensure that:

a. Transportation plans and projects provide for timely implementation of SIP transportation control measures in accordance with 40 CFR 93.113;

b. Transportation plans and projects comply with the fiscal constraint element per 40 CFR 93.108;

c. The MPO's interagency consultation procedures meet applicable requirements of 40 CFR 93.105;

d. Conformity of transportation plans is determined no less frequently than every four years, and conformity of plan amendments and transportation projects is demonstrated in accordance with the timing requirements specified in 40 CFR 93.104;

e. The latest planning assumptions and emissions model are used as set forth in 40 CFR 93.110 and 40 CFR 93.111;

f. Projects do not cause or contribute to any new localized carbon monoxide or particulate matter violations, in accordance with procedures specified in 40 CFR 93.123; and

g. Project sponsors and/or operators provide written commitments as specified in 40 CFR 93.125.

EPA meets at least annually with the Washington Department of Ecology, the Southwest Clean Air Agency, the Federal Highway Administration, the Southwest Washington Regional Transportation Council, and the Washington Department of Transportation to review documentation and the Transportation Improvement Plan for the Vancouver area and determine if the area is meeting the transportation conformity requirements under 40 CFR part 93. Vancouver is currently meeting the requirements under 40 CFR part 93, subpart A.

On November 19, 2007, EPA posted a notice finding the Vancouver CO second 10-year maintenance plan adequate for transportation conformity purposes. (See 72 FR 65019.)

VII. Final Action

In accordance with the requirements of the Federal Clean Air Act (the Act), EPA is approving this revision to the State Implementation Plan (SIP) because the State adequately demonstrates that the Vancouver Air Quality Maintenance Area will maintain air quality standards for CO through the year 2016. EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective August 26, 2008 without further notice unless the Agency receives adverse comments by July 28, 2008.

If EPA receives such comments, then EPA will publish a timely withdrawal of the direct final rule informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this rule. Any parties interested in commenting on this rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on August 26, 2008 and no further action will be taken on the proposed rule.

VIII. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the 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 August 26, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 10, 2008.

Michelle Pirzadeh,

Acting Regional Administrator, EPA Region 10.

■ For the reasons set out in the preamble, title 40, chapter I of the 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 WW—Washington

■ 2. Section 52.2475 is amended by adding paragraph (a)(4) to read as follows:

§ 52.2475 Approval of plans.

(a) * * *

(4) Vancouver.

(i) EPA approves as a revision to the Washington State Implementation Plan, the Vancouver Air Quality Maintenance Area Second 10-year Carbon Monoxide Maintenance Plan submitted by the Washington Department of Ecology on April 25, 2007.

(ii) [Reserved]

* * * * *

[FR Doc. E8–14518 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 401

[CMS–6032–F]

RIN 0938–AO27

Medicare Program; Use of Repayment Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule modifies Medicare regulations to implement section 935(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 pertaining to the use of repayment plans (also known as extended repayment schedules or ''ERS'') for Medicare provider and supplier overpayments. Under this provision, we are granting a provider or a supplier an ERS under certain terms and conditions as defined in the statute. This final rule establishes criteria and procedures to apply this requirement and to define the concepts of ''hardship'' and ''extreme hardship.''

DATES: *Effective Date:* These regulations are effective on July 28, 2008.

FOR FURTHER INFORMATION CONTACT: Tom Noplock, (410) 786–3378.

SUPPLEMENTARY INFORMATION:

I. Background

A. Medicare Overpayment

Medicare overpayments are Medicare funds an individual, provider, or supplier has received that exceed amounts due and payable under the Medicare statute and regulations (plus any applicable interest and penalties assessed on the overpayment). Section 400.202 defines a ''supplier'' as ''a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.''

Generally, overpayments result when payment is made by Medicare for items or services that are not covered, exceeds the amount allowed by Medicare for an item or service, or is made for items or services that should have been paid by another insurer (for example, Medicare secondary payer obligations). Once a determination and any necessary adjustments in the amount of the overpayment have been made, the remaining amount is a debt owed to the United States Government.

Section 1870 of the Social Security Act (the Act) provides a framework within which liability for such Medicare overpayments is determined and recoupment of overpayments is pursued. This framework prescribes a decision making process that the agency follows when pursuing the recoupment of Medicare overpayments.

The regulation governing the liability for Medicare overpayments is located at 42 CFR part 401 (subpart F).

B. Statutory Authority

The Federal Claims Collection Act of 1966 (Pub. L. 89–508) (FCCA), 80 Stat. 308 (amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA) (codified at 31 U.S.C. 3711)) is the Federal government's basic statutory authority for debt management practices. The Congress intended the FCCA to reduce the amount of litigation previously required to collect claims and to reduce the volume of private relief legislation in the Congress. The FCCA was intended to be independent of the other authorities we use to collect debt and added to, rather than supplanted, our other authorities, including common law authority.

The FCCA authorized the head of an agency to collect claims in any amount. This statute also provided that the head of an agency may, under certain conditions, compromise a claim, or suspend or terminate collection action on a claim. Uncollectible claims in excess of $100,000, exclusive of interest, must be referred to the Department of Justice for compromise. The FCCA was amended in 1996 and is now referred to as the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711).

In the November 2, 1977 **Federal Register** (42 FR 57351), the Secretary of the Department of Health and Human Services (the Secretary) published a rule to delegate authority to the Department Claims Officer generally, and the Administrator of the Centers for Medicare & Medicaid Services (the Administrator) for necessary claims collection actions under our programs. The authority delegated to the Administrator covers all of our activities in the Medicare program (Title XVIII) and pertains to claims up to $20,000. (This amount has been increased to $100,000; see 31 U.S.C. 3711.)

In the August 29, 1983 **Federal Register** (48 FR 39060), we published the ''Federal Claims Collection Act; Claims Collection and Compromise'' final rule with comment period in accordance with the FCCA. In that final rule with comment period, we adopted the applicable debt collection tools made available to us under the FCCA including the ability to collect or compromise claims, or suspend or terminate collection action, as appropriate. The final rule with comment period also set forth the requirements we use to evaluate debtors' requests for extended repayment agreements specified in § 401.607.

As part of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA), the Congress added section 1893 to the Act establishing the Medicare integrity program (MIP) to carry out Medicare program integrity activities that are funded from the Medicare Trust Funds. Section 1893 of the Act expands our contracting authority to allow us to contract with eligible entities to perform MIP activities. These activities include review of provider and supplier activities including medical, fraud, and utilization review; cost report audits; Medicare secondary payer determinations; education of providers, suppliers, beneficiaries, and other persons regarding payment integrity and benefit quality assurance issues; and developing and updating a list of durable medical equipment items that are subject to prior authorization (42 U.S.C. 1395ddd). These MIP contractors assist us in the identification and collection of Medicare provider and supplier overpayments.

C. Overview of Current Policy

The current policy that CMS and its contractors use for the evaluation of extended repayment schedules (ERSs) is based on the existing regulations at § 401.607(c)(2) and guidance in the Medicare Financial Management Manual, Pub. 100–6 (Chapter 4, Section 50). Under our current policy, we determine the frequency and amount of the installment payments based on the factors set forth at the current § 401.607(c)(2) which include the following: (1) The amount of the claim; (2) the debtor's ability to pay; and (3) the cost to CMS of administering an installment agreement.

Under the current ERS review process, we primarily focus on the second factor, the debtor's ability to repay the overpayment, by conducting a review of the debtor's financial status, similar to how banks assess applicants for a loan. In almost all cases, we try to work with the provider or supplier to recover the overpayment. In general, it has been our experience that it is in both CMS and the debtor's best interests to work out a reasonable repayment schedule to recoup an overpayment rather than demand immediate collection of the debt within 30 days, which could place a provider or supplier at financial risk or bring the provider or supplier a step closer to bankruptcy.

Under our existing procedures we review financial documentation submitted by the provider or supplier to assess the provider's or supplier's ability to repay the Medicare overpayment. This documentation must include, at a minimum, a statement of financial position (for example, a balance sheet), a statement of financial performance (for example, an income statement), and a statement of future viability (for example, a projected statement of cash flow). In addition, the provider must include a letter from a financial institution proving that it cannot obtain financing from an alternative source.

D. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

On December 8, 2003, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA). This legislation contained provisions affecting the recovery of provider and supplier overpayments under the Medicare program. Section 935(a) of the MMA amended title XVIII of the Act by adding a new section 1893(f)(1) to the Act to require us to use certain statutory criteria in evaluating whether a provider or supplier should be granted a repayment schedule of at least 6 months and up to 5 years.

II. Provisions of the Proposed Regulations

The following is an overview of the provisions we proposed in the Use of Repayment Plans proposed rule published in the November 27, 2006 **Federal Register** (71 FR 68519).

1. Hardship Provision

Under section 1893(f)(1) of the Act, we may grant a provider or a supplier upon request, a repayment schedule of at least 6 months, if repaying an overpayment within 30 days would constitute a ''hardship'' on the provider or supplier, provided that certain criteria are met.

The new statute at section 1893(f)(1)(B)(i) of the Act defines ''hardship'' based on the relationship between the amount of the Medicare overpayment(s) not covered under an existing ERS owed by a provider or supplier and the total amount of Medicare payments made to that provider or supplier over the most recently submitted cost report or for the previous calendar year.

Under section 1893(f)(1)(B) of the Act, a provider or supplier's repayment of an overpayment within 30 days is deemed to be a ''hardship'' when the total amount of all outstanding overpayments not included in an approved existing repayment schedule is 10 percent or greater than the total Medicare payments made for the cost reporting period covered by the most recently submitted cost report (for a provider filing a cost report), or the previous calendar year (for a supplier or non cost report provider). We proposed to interpret ''outstanding overpayments'' to include both principal and accrued interest. We read the newly added section 1893(f)(1)(B)(iii) of the Act to exclude overpayments already being repaid under an approved ERS.

We proposed to interpret the new ''hardship'' test under section 935(a) of the MMA as not to supersede our ERS regulations currently at § 401.607(c)(2), (which we proposed to redesignate as § 401.607(c)(3)). Since our existing regulations governing ERSs are issued under the FCCA, we do not plan to eliminate the criteria and procedures currently used to grant providers and suppliers ERSs. Instead, we proposed to add an initial ''hardship'' test to existing regulations and procedures for determining a debtor's ERS.

We proposed that all requests for an ERS first be evaluated under the new ''hardship'' test. Under section 935(a) of the MMA, if ''hardship'' is determined and no statutory exception applies under § 401.607(c)(2)(iv), then the statute requires that the Secretary grant a provider or supplier a repayment period of at least 6 months but not longer than 3 years.

Section 935(a) of the MMA requires that the Secretary establish rules for cases when a provider or a supplier was not paid during the previous year or paid for only a portion of that year. For these cases, we proposed to use the last 12 months of Medicare payments made to the provider or supplier. In cases where there is less than a 12-month payment history, we proposed that the number of months available be annualized to equal an approximate yearly Medicare payment level for the provider or supplier. (For detailed examples on how to apply the new ''hardship'' test provided in section 1893(f)(1) of the Act, please see the November 27, 2006 proposed rule, ''Use of Repayment Plans'' (71 FR 68521).)

2. Exceptions Under the ''Hardship'' Provision in Section 935(a) of the MMA

Section 935(a) of the MMA sets out exceptions to granting a provider or supplier an extended repayment schedule even if the provider or supplier meets the ''hardship'' test. These exceptions occur when there is reason to suspect the provider or supplier may file for bankruptcy, cease to do business, discontinue participation in the program, or when there is an indication of fraud or abuse committed against the program. (We proposed that contractors continue to use existing procedures and definitions applicable to bankruptcy and fraud or abuse.) In such cases, CMS or its contractors are prohibited from granting an ERS.

3. Extreme Hardship Provision

Under the provisions of § 401.607(c)(2)(vi) of this final rule, the Secretary may grant a provider or a supplier a repayment schedule of 36 months and up to 60 months if repaying an overpayment would constitute an ''extreme hardship'' unless a statutory exception applies under § 401.607(c)(2)(iv). Since the Congress left the definition of ''extreme hardship'' to our discretion, we considered different approaches for defining ''extreme hardship'' and sought public comment on this section.

We considered proposing a new financial threshold to determine if a provider or supplier was in extreme financial hardship, such as using a 15 percent threshold. We rejected this

approach because it could result in discriminating against providers and suppliers who may be similarly financially situated but may attribute more of their total revenue to Medicare income. This could occur for example with a home health agency (HHA) which may attribute 100 percent of its revenue to Medicare business and a skilled nursing facility (SNF) which may only attribute 20 percent of its business to Medicare.

We proposed to define ''extreme hardship'' when a provider or supplier qualifies under the ''hardship'' provision defined above and the provider's or supplier's request for an ERS is approved under newly redesignated § 401.607(c)(3). If we determine the request meets the criteria in the redesignated § 401.607(c)(3) and meets the CMS manual guidance set forth in the Medicare Financial Management Manual, Pub. 100–6, Chapter 4, Section 50, we proposed that the provider or supplier may be granted an ERS between 36 and 60 months. We also proposed that contractors apply the statutory exceptions to ''extreme hardship'' cases in a similar manner as they do to ''hardship'' cases. We solicited comments on other alternative approaches to define ''extreme hardship'' that could distinguish between the most extreme cases requiring ERSs between 36 and 60 months.

4. Extended Repayment Schedules (ERSs)

We proposed to initially handle ERS requests differently than we have under our current regulations. We proposed to allow providers or suppliers that meet the ''hardship'' test and request only a 6-month ERS period, the opportunity to pay back the Medicare debt in 6 months without having to submit financial documentation to the contractor in accordance with the existing instructions in the Medicare Financial Management Manual, CMS, Pub. 100–6, Chapter 4, Section 50. We believe that by waiving the requirement to submit financial documentation (such as financial statements or a bank denial letter) for a 6-month ERS, we allow a provider or supplier time to generate or secure the necessary capital to liquidate the debt without having to file extensive documentation in order to secure a repayment schedule.

We therefore proposed that a provider or supplier that requests a 6-month ERS, meets the ''hardship'' test, does not fall within an exception, and elects not to submit financial documentation would be approved for a 6-month ERS. Any provider or supplier qualifying for the 6-month ERS under the ''hardship'' provision has the choice to turn down the 6-month ERS and either pay off the debt within 30 days of the date of determination or request a longer than 6-month ERS. In addition, we proposed not to prohibit any provider or supplier under the 6-month ''hardship'' provision ERS from applying for a longer ERS if it later desires to do so under § 401.607(c)(3).

For all ERS requests greater than 6 months, we proposed to rely on current regulations and procedures that require the provider or supplier to submit financial documentation in accordance with the Medicare Financial Management Manual, CMS Pub. 100–6, Chapter 4, Section 50. A provider or supplier must continue to submit a written request that refers to the specific overpayment for which an ERS is being requested, the number of months requested in the ERS, and include the first payment with its request. The contractor would determine the duration of the ERS based on its review of the provider or supplier's documentation in accordance with CMS manual guidance.

If a provider or supplier misses one installment payment in any ERS granted under section 935(a) of the MMA, the statute permits us to immediately collect the entire overpayment. However, we proposed to impose this penalty only on the ''automatic'' 6-month ERS. With all other ERSs, we proposed to continue to use the existing procedures that define a default of an ERS as missing two consecutive installment payments.

We proposed to revise § 401.601(a) to read as follows: ''This subpart implements the following provisions: (1) For CMS the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711), and conforms to the regulations (31 CFR parts 900–904) issued jointly by the Department of the Treasury and the Department of Justice that generally prescribe claims collection standards and procedures under the DCIA for the Federal government; (2) section 1893(f)(1) of the Act regarding the use of repayment plans.''

In addition, in § 401.603 we proposed to add a definition for an ''extended repayment schedule.''

We proposed to redesignate § 401.607(c)(2) as § 401.607(c)(3). In addition, we proposed a new § 401.607(c)(2), Extended repayment schedule, in accordance with section 1893(f)(1) of the Act. We proposed to implement the provisions of section 1893(f)(1) of the Act, as amended by section 935(a) of the MMA, in new § 401.607(c)(2), Extended repayment schedule.

III. Analysis of and Responses to Public Comments

We received 6 public comments on the November 27, 2006 proposed rule. The following is a summary of the major issues and our responses.

Comment: One commenter believed that the provisions of the proposed rule were not equitable between provider types because 10 percent of total Medicare reimbursement for a provider with a 50 percent Medicare fee-for-service revenue is a greater threshold to reach than a provider with a 5 percent Medicare fee-for-service revenue.

Response: We agree with the comment that the proposed rule may not in all cases treat different provider types similarly. However, the statute was written to define hardship as a ratio of Medicare overpayments to total Medicare payments/reimbursement in a given time period. The statute does not allow CMS to take into account the percentage of patient revenue from other sources when defining ''hardship.'' For all other ERS requests, we proposed to rely on current regulations and procedures that require the provider or supplier to submit financial documentation in accordance with the Medicare Financial Management Manual, CMS Pub. 100–6, Chapter 4, Section 50.

Comment: Some commenters believed it would be more consistent and more fair to providers if we would use the definition of default for all ERSs as missing two consecutive installment payments.

Response: While the statute permits us to immediately collect on an entire overpayment if a provider or supplier misses one installment payment in any ERS granted under section 935(a) of the MMA, we have decided to impose the 1-month missed payment rule only for the 6-month ''hardship-based'' ERS. We chose not to apply the two missed payment rule to 6-month ERSs because we do not want a provider or supplier to be too far in arrears if they miss payments in such a short ERS. A provider or supplier that is behind two payments in a 6-month ERS has a greater amount of its payments in arrears than a provider or supplier that is behind two payments in a 36-month or 60-month ERS. For example, two missed payments on the amortization of an overpayment covered under a 6-month ERS (2 divided by 6) is equal to approximately 33.3 percent of the total overpayment whereas 2 missed payments under a 36-month ERS (2

divided by 36) is equal to a much lower 5.5 percent of the total overpayment. On a 60-month ERS, two missed payments would only equal 3.3 percent of the total overpayment (2 divided by 60).

Comment: Some commenters were concerned that we may be inadvertently legally binding providers to the ''automatic'' 6-month ERS and not offering providers a future opportunity to request a second ERS under § 401.607(c).

Response: In the proposed rule, we stated that any provider or supplier qualifying for the 6-month ERS under the ''hardship'' provision has the choice to turn down the 6-month ERS and either pay off the debt within 30 days of the date of determination or request a longer ERS under newly redesignated § 401.607(c)(3). In addition, we will not prohibit any provider or supplier under the 6-month ''hardship'' provision ERS from applying for a longer ERS if it later desires to do so under § 401.607(c)(3).

Comment: One commenter believed that there is no practical reason for why we have not adopted a parallel numerical threshold approach to extreme hardship by using some percentage above the numerical 10 percent threshold for hardship.

Response: The 10 percent used in this final rule to define hardship is required by statute. As stated in the proposed rule, we considered proposing a new financial threshold to determine if a provider or supplier was in extreme financial hardship, such as using a 15 percent threshold. However, we rejected this approach because it could result in discriminating against providers and suppliers who may be similarly financially situated but may attribute more of their total revenue to Medicare income. This could occur for example with a home health agency (HHA) which may attribute 100 percent of its revenue to Medicare business and a skilled nursing facility (SNF) which may only attribute 20 percent of its business to Medicare. In addition, the ERS review process is a multivariable financial analysis and it would not be practical or equitable to either the provider/supplier or the Medicare program to reduce the ERS process down to a single variable. We believe keeping the definition of extreme hardship broader than a single variable is in the best interests of the provider and supplier community and is the most effective way to ensure that overpayments will be collected and returned to the Medicare Trust Fund.

Comment: One commenter stated that there is confusion as to why the burden of producing financial documentation can be removed for the ''automatic'' 6-month ERS but not for ERS plans longer than 6 months.

Response: We removed the financial documentation requirement for 6-month ERSs because the contractor already has the requisite information needed to determine if a provider or supplier meets the statutory hardship test. However, in order to grant an ERS longer than 6 months, we continue to need financial documentation to determine a provider or supplier's ability to make future ERS payments. We also need financial data to determine the length of the ERS or payback period that should be granted to the provider or supplier. While a short ERS may cause a provider or supplier to go out of business, the longer the ERS period the greater the delay in the overpayment recovery and the greater the financial risk to the Medicare program. We believe the increased risk associated with a longer repayment or amortization period requires that we give an ERS request greater financial scrutiny.

Comment: We received comments that were outside the scope of the proposed rule (for example, regarding the effects on State Medicaid programs).

Response: We are not responding in this final rule to comments that are outside of the scope of the proposed rule.

IV. Provisions of the Final Regulations

As a result of our review of the public comments, we do not find any cause to alter the provisions of the proposed rule. Therefore, we are finalizing the provisions as proposed.

V. Collection of Information Requirements

This final rule does not impose any new information collection or recordkeeping requirements. The information collection requirements discussed in the preamble pertain to the extension of repayment schedules. The requirements and associated paperwork burden are approved under Office of Management and Budget (OMB) control number 0938–0270, with a current expiration date of January 31, 2011.

We plan to submit a revised information collection request (ICR) to OMB to address the reduction of burden associated with the ''hardship test'' and 6-month ERS period. As discussed in Section I. of the preamble, providers or suppliers that meet the ''hardship'' test and request only a 6-month ERS period, will have the opportunity to pay back the Medicare debt in 6 months without having to submit financial documentation to the contractor. This new requirement reduces the information collection burden placed on providers and suppliers. We will announce the revisions to 0938–0270 under separate notice and comment periods prior to submitting the revisions for OMB approval.

VI. Regulatory Impact Statement

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), 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 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 final rule will not reach the economic threshold and thus is not considered a major rule. There will be no additional costs or documented savings resulting from the implementation of this final 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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. For purposes of the RFA, approximately 95 percent of the health care industry is considered small businesses according to the Small Business Administration's size standards with total revenues of $6.5 million to $31.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. Because there are no additional costs or documented savings resulting from the implementation of this rule, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a

significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Because there are no additional costs or documented savings resulting from the implementation of this final rule, this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $127 million. This final rule will not impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of $127 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a 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 final rule will not have a substantial effect on State or local governments.

B. Anticipated Effects

1. Effects on Medicare Providers and Suppliers

This final rule could affect all Medicare provider and supplier types with a Medicare overpayment. This final rule will allow Medicare providers or suppliers falling within these provisions a 6 month period to pay back debt owed to Medicare without being required to file extensive financial documentation. We believe that this short repayment time period could provide a provider or supplier time to generate or secure the necessary capital to liquidate the debt without having to file the financial documentation required to secure a longer repayment schedule.

2. Effects on Other Providers

There will be no effect on other providers.

3. Effects on the Medicare and Medicaid Programs

There will be no additional costs or documented savings resulting from the implementation of this final rule. There may be savings due to a possible reduction in paperwork.

C. Alternatives Considered

We considered adopting mathematically precise distinctions between ''hardship'' and ''extreme hardship,'' but rejected this approach. To select any type of numerical threshold, for example, defining ''extreme hardship'' as 15 percent of total overpayments in an effort to distinguish it from the test for ''hardship,'' will result in inequitable outcomes for different providers and suppliers as discussed in the ''extreme hardship'' section in section II. of this final rule, Provisions of the Proposed Regulations.

In implementing section 935(a) of the MMA, we want to assure providers and suppliers that we will be looking closely at the financial picture each of them has that has prompted them to seek an ERS. Analyzing these financial profiles is a complex undertaking that does not lend itself to overly simplified numerical cutoffs that may qualify some for longer repayment periods but deny them to others that ought to be just as eligible. We solicited comments on other alternative ways to distinguish between ''hardship'' and ''extreme hardship'' in an effort to establish a standardized approach to applying the two definitions.

D. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart F—Claims Collection and Compromise

■ 2. In § 401.601, paragraph (a) is revised to read as follows:

§ 401.601 Basis and scope.

(a) *Basis.* This subpart implements the following statutory provisions:

(1) For CMS the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711), and conforms to the regulations (31 CFR parts 900–904) issued jointly by the Department of the Treasury and the Department of Justice that generally prescribe claims collection standards and procedures under the DCIA for the Federal government.

(2) Section 1893(f)(1) of the Act regarding the use of repayment plans.

* * * * *

■ 3. In § 401.603, add a new definition for ''Extended repayment schedule'' to read as follows:

§ 401.603 Definitions.

* * * * *

Extended repayment schedule means installment payments to pay back a debt.

§ 401.607 [Amended]

■ 4. In § 401.607—

■ A. Redesignate paragraph (c)(2) as paragraph (c)(3).

■ B. Add a new paragraph (c)(2).

The addition reads as follows:

§ 401.607 Claims collection.

* * * * *

(c) * * *

(2) *Extended repayment schedule.*

(i) For purposes of this paragraph (c)(2), the following definitions apply:

Extreme hardship exists when a provider or supplier qualifies as being in ''hardship'' as defined in this paragraph and the provider's or supplier's request for an extended repayment schedule (ERS) is approved under paragraph (c)(3) of this section.

Hardship exists when the total amount of all outstanding overpayments (principal and interest) not included in an approved, existing repayment schedule is 10 percent or greater than the total Medicare payments made for the cost reporting period covered by the most recently submitted cost report for a provider filing a cost report, or for the previous calendar year for a supplier or non cost-report provider.

(ii) CMS or its contractor reviews a provider's or supplier's request for an ERS. For a provider or a supplier not paid by Medicare during the previous year or paid only during a portion of that year, the contractor or CMS will use the last 12 months of Medicare payments. If less than a 12-month payment history exists, the number of months available is annualized to equal an approximate yearly Medicare payment level for the provider or supplier.

(iii) For a provider or supplier requesting an ERS, CMS or its contractor

evaluates the request based on the definitions and information submitted under this paragraph (c)(2). For a provider or supplier whose situation does not meet the definitions in paragraph (c)(2)(i) of this section, CMS or its contractor evaluates the ERS request using the information in paragraph (c)(3) of this section in deciding to grant an ERS.

(iv) CMS or its contractor is prohibited from granting an ERS to a provider or supplier if there is reason to suspect the provider or supplier may file for bankruptcy, cease to do business, discontinue participation in the Medicare program, or there is an indication of fraud or abuse committed against the Medicare program.

(v) CMS or its contractor may grant a provider or a supplier an ERS of at least 6 months if repaying an overpayment within 30 days will constitute a ''hardship'' as defined in paragraph (c)(2)(i) of this section. If a provider or supplier is granted an ERS under this paragraph, missing one installment payment constitutes a default and the total balance of the overpayment will be recovered immediately.

(vi) CMS or its contractor may grant a provider or a supplier an ERS of 36 months and up to 60 months if repaying an overpayment will constitute an ''extreme hardship'' as defined in paragraph (c)(2)(i) of this section.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: *January 22, 2008.*

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: *February 27, 2008.*

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on June 11, 2008.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, and 498

[CMS–6003–F]

RIN 0938–AI49

Medicare Program; Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements a number of regulatory provisions that are applicable to all providers and suppliers, including durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers. This final rule establishes appeals processes for all providers and suppliers whose enrollment, reenrollment or revalidation application for Medicare billing privileges is denied and whose Medicare billing privileges are revoked. It also establishes timeframes for deciding enrollment appeals by an Administrative Law Judge (ALJ) within the Department of Health and Human Services (DHHS) or the Departmental Appeals Board (DAB), or Board, within the DHHS; and processing timeframes for CMS' Medicare fee-for-service (FFS) contractors.

In addition, this final rule allows Medicare FFS contractors to revoke Medicare billing privileges when a provider or supplier submits a claim or claims for services that could not have been furnished to a beneficiary. This final rule also specifies that a Medicare contractor may establish a Medicare enrollment bar for any provider or supplier whose billing privileges have been revoked.

Lastly, the final rule requires that all providers and suppliers receive Medicare payments by electronic funds transfer (EFT) if the provider or supplier, is submitting an initial enrollment application to Medicare, changing their enrollment information, revalidating or re-enrolling in the Medicare program.

DATES: *Effective Date:* These regulations are effective on August 26, 2008.

FOR FURTHER INFORMATION CONTACT: August Nemec, (410) 786–0612.

SUPPLEMENTARY INFORMATION:

I. Background

A Medicare beneficiary may obtain covered Medicare items or services from any person, or institution that is enrolled in the Medicare program and is qualified to furnish those services. Various provisions of the statute and regulations establish conditions of participation or standards that a healthcare provider or supplier must meet in order to receive Medicare payment. These standards differ depending on the type of provider or supplier involved and whether the services are furnished under Parts A or B of the Medicare statute. There are also differences in qualifications between providers and suppliers of services, and differences among the various types of suppliers, in how they are enrolled in the Medicare program. For some classifications of providers and suppliers, an on-site survey is required. For other individuals or entities, a determination can be made based largely on the information provided by the applicant.

The Medicare regulations in 42 CFR part 498 provide appeal rights for providers and suppliers that have been found to not meet certain conditions of participation or established standards. For the purposes of part 498, these suppliers include, but are not limited to, independent laboratories; suppliers of portable x-ray services; rural health clinics; federally qualified health centers; ambulatory surgical centers; entities approved by CMS to furnish outpatient diabetes self-management training or end-stage renal disease treatment facilities. For the purposes of part 498, the term ''provider'' refers to a hospital, critical access hospital (CAH), skilled nursing facility, comprehensive outpatient rehabilitation facility (CORF), home health agency or hospice (HHA), religious nonmedical health care institutions (RNHCIs) that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

In addition, § 405.874 provides an appeals process for suppliers of DMEPOS that wish to contest a denial of an application for billing privileges or the revocation of existing billing privileges. It also affords DMEPOS suppliers the right to a carrier or Medicare Administrative Contractor (MAC) hearing before an official who was not involved in the original determination, and the right to seek a review before a CMS official designated by the CMS Administrator.

In December 1998, we issued CMS Ruling 98–1, which outlined the appeals process that Medicare carriers must provide to physicians, nonphysician practitioners, and to certain entities that receive reassigned benefits from physicians and nonphysician practitioners. CMS Rulings are decisions of the Administrator that serve as precedent for final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of statute or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters. CMS Rulings are binding on all our components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and ALJs who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes. This final rule is different from the clarification of appeals procedures found in CMS Ruling 98–1, because it adds provisions in order to comply with the MMA. Whereas the ruling followed the procedures in § 405.874, this final rule would grant suppliers the right, after denial or revocation of a supplier's Medicare billing privileges, to a hearing by an ALJ after an adverse decision at the reconsideration level, as well as judicial review.

In the October 25, 1999 **Federal Register** (64 FR 57431), we published a proposed rule Appeals of Carrier Terminations that a Supplier Fails to Meet the Requirements for Medicare Billing Privileges that would revise § 405.874 by extending appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under existing appeals provisions of our regulations.

Since we did not publish our earlier rulemaking effort within 3 years as required by section 902 of the MMA, we published a new proposed rule on March 2, 2007. This proposed rule included changes mandated by section 936(a) and (b) of the MMA.

II. Provisions of the March 2, 2007 Proposed Rule

In the March 2, 2007 **Federal Register** (72 FR 9479), we published a proposed rule that set forth standard provider and supplier appeal procedures as established in section 936 of the MMA and proposed certain other provisions associated with Medicare's provider and supplier enrollment process. We proposed to maintain § 405.874, which specifies provisions that would apply to certain suppliers as defined in § 405.802. In § 405.802, we proposed to define prospective supplier and suppliers by specifying the provisions of § 405.874 that would apply. In § 405.874(a), we proposed that if a CMS contractor (that is, a carrier, fiscal intermediary or Medicare administrative contractor (MAC)) denies a supplier's enrollment application, the CMS contractor must notify the supplier by certified mail. The notice must include the following: (1) The reason for the denial in sufficient detail to allow the supplier to understand the nature of its deficiencies; (2) the right to appeal in accordance with part 498; and (3) the address to which the written appeal must be mailed.

In § 405.874(b)(1), we proposed to clarify that if a carrier revokes a supplier's Medicare billing privileges that the carrier must notify the supplier by certified mail and that the notice must include—(1) The reason for the revocation in sufficient detail for the supplier to understand the nature of its deficiencies; (2) the right to appeal in accordance with part 498 of this chapter; (3) the address to which the written appeal must be mailed.

In § 405.874(b)(2), we proposed to separate the procedures in existing § 405.874(a) and § 405.874(b). In § 405.874(b)(2), we proposed clarifying that a revocation of a supplier billing privileges that is based on a Federal exclusion or debarment is effective with the effective date of the exclusion or debarment, regardless of the date of the notice from the carrier that the billing privileges are revoked. Moreover, if CMS, or one of its designated contractors revokes Medicare billing privileges, we would not revoke an individual or organization's National Provider Identifier (NPI).

In § 405.874(b)(3), we proposed clarifying that suppliers are not paid for items or services furnished during a period in which a supplier does not have billing privileges or its billing privileges have been revoked. Concerning DMEPOS suppliers, section 1834(j)(1) of the Social Security Act (the Act) states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items and supplies unless the supplier has active Medicare billing privileges. We further proposed that claims submitted to CMS contractors for items or services furnished during a period of supplier ineligibility are to be rejected by the CMS contractor, not denied.

In § 405.874(c)(1), we proposed that a supplier's appeal rights would follow the processes detailed in part 498. In § 405.874(d), we proposed to revise this section to reflect that claims for services furnished to Medicare beneficiaries during a period in which the supplier's billing privileges were not effective are rejected and not denied. If a provider or supplier is determined not to have qualified for billing privileges in one period but qualified in another, contractors process claims for services furnished to beneficiaries during the period for which the provider or supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for recovery of overpayments. The appeals process for denied claims should not apply if a provider or supplier does not have billing privileges.

In § 405.874(d)(3), we proposed if a revocation of a provider's or supplier's billing privileges is reversed upon appeal, the provider's or supplier's billing privileges are reinstated back to the date that the revocation became effective.

In § 405.874(d)(4), we proposed that if a denial of a provider's or supplier's billing privileges is reversed upon appeal, then the appeal decision establishes the date that the provider's or supplier's billing privileges will become effective.

In § 405.874(e), we proposed that if a provider or supplier completes a corrective action plan and provides sufficient evidence to the CMS contractor that it has complied fully with Medicare requirements, the CMS contractor may reinstate the supplier's billing privileges.

In § 405.874(f), we proposed revising the effective date for DMEPOS supplier's billing privileges. If a carrier, carrier hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in § 424.57 of this chapter and any other requirements that may apply (for example, reinstatement after an OIG exclusion), the determination establishes the effective date of the billing privileges as not earlier than the date the CMS contractor made the determination to deny the supplier's enrollment application. Claims are rejected for services furnished before that effective date.

In § 405.874(g), we proposed that a provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed, or in having its billing privileges reinstated, may submit claims to the

CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims.

In § 405.874(h), we proposed establishing deadlines for the adjudication of provider enrollment actions. We proposed that contractors adjudicate initial determinations and revalidations within 180 days of receipt and carriers adjudicate change-of-information and reassignment of payment request within 90 days of receipt. In addition, we proposed to establish timeframes for each administrative level of appeal. The following table identifies who makes the determinations and the associated timeframes in which each determination is made.

Medicare provider enrollment determination	Timeframe to file an appeal (days)	Proposed maximum adjudication timeframe (days)
Initial	60	180
Reconsideration	60	60
Administrative Law Judge Review	60	180
Departmental Appeals Board Review	60	180
Federal District Court	N/A	N/A

In § 424.510(d)(2)(iv), we proposed that at the time of enrollment, an enrollment change request or revalidation, providers and suppliers shall submit the CMS–588 form to receive payments via electronic funds transfer.

In § 424.545(a), we proposed the following:

- Redesignating the first sentence of current paragraph (a) as the introductory text and revising that text to remove the reference to part 405 subpart H.
- Redesignating the second sentence of current paragraph (a) as paragraph (a)(1)(i).
- Adding paragraph (a)(1)(ii) to clarify that if a provider appeals both of these sanctions, then both matters will be resolved using a single appeals process.
- Redesignating the last sentence of current paragraph (a) as paragraph (a)(2).

In § 424.525(a)(1) and (a)(2), we proposed potential reasons for rejecting enrollment applications by reducing the amount of time that a provider or supplier must furnish complete information requested by a contractor from 60 to 30 days. Additionally, we proposed a reduction from 60 to 30 days for the period allowed to furnish all supporting documentation for submitting their enrollment application.

We proposed rejecting an application that is submitted by a provider or supplier if it is incomplete or if it fails to include all required supporting documentation on the enrollment application within 30 days of receipt.

In § 424.535(a)(8), we proposed allowing Medicare FFS contractors, under the direction of CMS, to revoke Medicare billing privileges when a provider or supplier submits a claim or claims for services that could not have been furnished to a beneficiary.

In § 424.535(b)(2), we proposed a timeframe to wait for reapplication to the Medicare program when a provider or supplier is revoked. Specifically, we proposed that when a provider or supplier, including all authorized officials, delegating officials and practitioners, is revoked for any of the reasons listed at § 424.535 that the provider, supplier, delegated official or authorizing official be prohibited from enrolling for 3 years.

In § 498.1(g), we proposed to establish an ALJ hearing, and judicial review for any provider or supplier whose application for enrollment or reenrollment in Medicare has been denied.

In § 498.2, we proposed revising the definition of a ''supplier'' to—(1) Include a supplier of DMEPOS; ambulance service provider; independent diagnostic testing facility; physician; and other practitioner such as physician assistant; and (2) remove the reference to ''prospective supplier.''

In § 498.2, we proposed adding a new definition for ''prospective supplier.''

We also proposed removing the definition of the ''Office of Hearings and Appeals (OHA)'' because the function of this office has been moved from the Social Security Administration to the DHHS. We also proposed to revise the definition of ''affected party'' to specify that it includes CMS or a CMS contractor.

In § 498.5, we proposed revising this section by adding a new paragraph (l) that would be used to clarify the administrative process that a prospective provider, existing provider, prospective supplier or existing supplier dissatisfied with an initial determination or revised initial determination related to the denial or revocation of Medicare billing privileges.

We proposed revising § 498.5(f)(2) to be consistent with the change in § 498.1(g). This would implement the mandate of section 936(a)(2) of the MMA regarding judicial review. We proposed these standards because the FFS contractors need sufficient time to adjudicate the facts and make a reasoned decision. Moreover, while we are establishing an outside limit for processing these applications, the vast majority of these decisions are made within 120 days.

We proposed revising § 498.22(a) to add that we have delegated authority to our contractors to reconsider an initial determination. We also proposed revising § 498.22(b)(1) to state that a reconsideration request is to be filed with CMS or with the State survey agency, or, in the case of prospective suppliers, the entity specified in the notice of initial determination.

We proposed revising § 498.44 to remove the term Associate Commissioner for Hearings and Appeals, and we replaced it with the Secretary, because this function is no longer under the Social Security Administration; it is now under the Department of Health and Human Services.

In § 405.874(c)(2), we proposed clarifying that a provider or supplier is required to prove that it is in compliance with all Medicare requirements for billing privileges, and that the Medicare FFS contractor incorrectly denied or revoked the supplier's billing privileges. In § 498.56, we proposed adding a new paragraph (e) that specifies the ''good cause'' exception to the admission of new evidence at the ALJ and DAB appeal levels. Accordingly, we proposed revising § 498.56 and § 498.86 to prohibit providers and suppliers from submitting new provider enrollment

issues or evidence at the ALJ and DAB levels of review.

In § 498.78(a), we proposed to delete the provision that an affected party concur in writing or on the record with a CMS or Department of Health and Human Services Office of Inspector General (OIG) request for remand. We believe that the appeals process can be enhanced by allowing an ALJ to remand a provider enrollment case to the Medicare FFS contractor when CMS requests a remand. Further, we believe that a remand request could result in either a favorable decision to the appellant or an administrative record that is complete.

In § 498.79, we proposed that an ALJ must issue a decision, dismissal order or remand to CMS, as appropriate, no later than 180 days after the initial request for a hearing.

Finally, in § 498.88(g), we proposed that the Board must issue a decision, dismissal order or remand to the ALJ, as appropriate, no later than 180 days after the appeal was received by the Board.

III. Analysis of and Responses to Public Comments

We received approximately 30 comments in response to the March 2, 2007 proposed rule. The following is a summary of the comments received and our responses.

Comment: Several commenters recommended that we clarify whether the provisions of the proposed rule apply to all providers and suppliers.

Response: The provisions of the proposed and this final rule apply to all the providers and suppliers described in the § 405.802 or § 498.2. Therefore, in response to comments received, we are adding definitions for ''prospective supplier'' and ''prospective provider'' to § 405.802 and § 498.2. Since applicants (prospective provider and suppliers) who are not enrolled in the Medicare program still are afforded appeal rights based on an enrollment denial, we maintain that it is important to clarify that any prospective applicant (provider or supplier) is afforded appeal rights through this process.

Comment: One commenter recommended that we separately define ''prospective provider'' and modify the definition of provider accordingly.

Response: We agree with the commenter's recommendations and have included a definition of ''prospective provider'' in § 405.802 and 498.2 and have revised the definition of ''provider'' at § 405.802 and § 498.2.

Comment: One commenter suggested that we change the definition of supplier to include occupational therapists in private practice.

Response: This comment falls outside the scope of the proposed rule. Therefore, we believe it would be inappropriate for us to address this comment in this final rule.

Comment: Several commenters recommended that we clarify whether a provider or supplier who uses a corrective action plan (CAP) is precluded from also appealing the contractor, carrier, MAC, or FI decision.

Response: A CAP is the plan that allows a provider or supplier an opportunity to correct deficiencies (if possible) that resulted in a denial or revocation of billing privileges. The CAP should provide evidence that the provider or supplier is in compliance with Medicare enrollment requirements. A provider or supplier that uses a CAP is not precluded from also appealing the FFS contractor's (that is in a MAC, FI, or carrier) decision. The Medicare FFS contractor, including the National Supplier Clearinghouse (NSC), will accept the submission of a corrective action plan for revoked billing privileges if the corrective action plan is submitted within 15 days from the date of the notice for DMEPOS suppliers or within 30 days from the date of the notice for all other providers and suppliers.

Comment: Several commenters recommended that we clarify that an independent contractor hearing officer will conduct the reconsideration of an adverse enrollment decision.

Response: For the purpose of this final rule, the term an independent contractor hearing officer means that a reconsideration will be handled by a hearing officer not involved in the initial determination. We believe this will ensure that the appellant receives a fair and impartial reconsideration. It is also important to note that while the claims appeals process uses a ''qualified independent contractor'' to conduct reviews, the provider enrollment appeals process does not use a ''qualified independent contractor.''

Comment: Several commenters recommended that we clarify when a provider or supplier may resubmit a new initial enrollment application after an enrollment denial.

Response: Since the denial of enrollment application conveys appeal rights, a provider or supplier cannot resubmit a new initial enrollment application until after the 60 day appeal period has ended. This will ensure that the Medicare contractor is not processing an initial application during the timely filing period of an appeal. In addition, if a provider or supplier submits a new initial enrollment application during the timely appeals filing period, the Medicare contractor will return the application to the applicant.

Comment: One commenter recommended that we change our proposed language concerning a remand by an ALJ to specify that CMS does not have authority to request a remand when the Agency is also a party to an ALJ proceeding.

Response: We believe that we should have all the rights afforded to an appellant. Further, by allowing CMS to request a remand, we believe that the designated contractor or CMS Regional Office will be able to review or re-examine the administrative record to update or provide documentation to establish a complete administrative record. By doing so, we believe higher levels of appeal will have the information needed to effectuate a timely decision. Therefore, we do not agree with the commenter's recommendation to revise the language to prohibit our authority to request a remand.

Comment: One commenter recommended that we adopt a 45-day time period for adjudication of ALJ and DAB decisions.

Response: We believe that a 45-day time period is not practical. While we understand the desire to establish an efficient appeals process, we are adopting similar time frames as had been established for deciding a claims appeal before an ALJ or DAB (see § 405.1016(c)). As stated previously, the early presentation of evidence will allow the contractor hearing officer or the CMS Regional Office to make decisions using all relevant facts as applied to the appeal. In doing so, the hearing officer or regional office will issue their findings to establish a complete administrative record for the future appeal levels. We believe that a complete administrative record will help facilitate decision making at higher levels of appeal.

Comment: Several commenters stated that a reconsideration is an unnecessary delay in the appeals process, and that applicants should be able to appeal directly to an ALJ.

Response: We determined that the most effective way to implement the requirements of section 936(j)(2) of the MMA was to amend the existing appeals procedures in part 498. The appeals procedures under part 498 include reconsideration as a level of review before an appeal is made to an ALJ. We believe that the reconsideration level provides an additional opportunity for the matter to be resolved prior to the filing of an appeal to an ALJ.

Comment: One commenter requested clarification of § 405.874(c)(2), which discussed the reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges.

Response: The reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges will be handled by a carrier hearing officer not involved in the initial determination or a CMS Regional Office for a Part A determination.

There are distinct appeals provisions for claims processing and provider enrollment. While the claims process uses claims determination and qualified independent contractors (QICs) as part of the appeals process, the provider enrollment process does not. The first level of appeal of adverse actions is to either a contractor hearing officer for noncertified suppliers or to the CMS Regional Office for certified providers or suppliers. Subsequently, appellants may appeal adverse provider enrollment determinations by a hearing officer or regional office to an ALJ, then the DAB, and then to Federal District Court.

Comment: One commenter recommended that § 498.86(a) concerning evidence admissible on review by the DAB, adopt and follow the good cause exception set forth in proposed § 498.56(e) for ALJ proceedings.

Response: By the time the DAB hears the provider enrollment appeal, the applicant has been afforded ample opportunity to submit any evidence germane to the adverse determination. Accordingly, we do not believe it is efficient or administratively effective to establish a ''good cause'' provision within the language at § 498.86(a).

Comment: While we received a number of comments supporting our proposal to prohibit providers and suppliers from submitting new evidence during the ALJ and DAB levels of appeal, several commenters stated they were opposed to this proposal.

Response: Consistent with the provisions of our April 21, 2006 final rule titled ''Requirements for Establishing and Maintaining Medicare Billing Privileges and Provider Enrollment Process'' (71 FR 20754), we believe all providers and suppliers must meet and maintain all Federal and State requirements for their provider or supplier type to enroll or maintain their enrollment in the Medicare Program.

When a Medicare contractor makes an adverse enrollment determination (for example, enrollment denial or revocation of billing privileges), providers and suppliers are afforded appeal rights. However, these appeal rights are limited to provider or supplier eligibility at the time the Medicare contractor made the adverse determination. Thus, if a Medicare contractor determines that a provider or supplier does not meet State licensure requirements on June 1, 2007, it is the provider's responsibility to demonstrate during the appeals process that State licensure requirements were met on June 1, 2007. Conversely, if a provider only can demonstrate that State licensure requirements were met on a later date; such as, August 16, 2007, we believe that the contractor made the correct determination, and that the provider or supplier may reapply for Medicare billing privileges. Accordingly, a provider or supplier is required to furnish the evidence that demonstrates that the Medicare contractor made an error at the time an adverse determination was made, not that the provider or supplier is now in compliance. Thus, we believe that it is essential that providers and suppliers submit documentation that supports their eligibility to participate in the Medicare program during the reconsideration step of the provider enrollment appeals process. This will allow a hearing officer to review and make a decision using all applicable facts. Moreover, the early presentation of evidence will help to ensure an efficient and effective administrative appeals process.

Finally, in order to expedite the provider enrollment appeals process, we believe that applicants must present all relevant facts and supporting documentation prior to or during the first level of appeal (that is, reconsideration). This will enable a contractor hearing officer or the CMS Regional Office personnel to review and make a determination based on all available facts. Moreover, the early presentation of facts and supporting documentation can be used to build the administrative record and help facilitate timely decisions at higher levels of appeals.

Comment: One commenter suggested that we continue to follow the existing ALJ and DAB procedures in part 498 to allow for consideration and for submission of additional evidence related to a provider or supplier enrollment appeal after the initial information is submitted.

Response: As stated previously in this final rule, in order to expedite the provider enrollment appeals process, we believe that applicants must present all relevant facts and supporting documentation prior to or during the first level of appeal (that is, reconsideration). This will enable a contractor hearing officer or the CMS Regional Office personnel to review and make a determination based on all available facts. Moreover, the early presentation of facts and supporting documentation can be used to build the administrative record and help facilitate timely decisions at higher levels of appeals.

Comment: Several commenters stated that we used the terms ''billing number'' and ''billing privileges'' interchangeably in the proposed rule and that caused confusion.

Response: We appreciate these comments and will revise the final rule to use the term ''billing privileges'' throughout. With the implementation of the National Provider Identifier on May 23, 2008, Medicare will no longer issue a billing number to providers and suppliers, but will, in fact, convey billing privileges to a provider or supplier if they meet and maintain all Federal and/or State requirements to enroll or remain enrolled in the Medicare program.

Comment: Several commenters recommended that physicians be allowed to appeal rejected claims once Medicare billing privileges are granted.

Response: Physicians, as well as providers and other suppliers, are required to enroll in the Medicare program before submitting a Medicare claim. Accordingly, if a claim is rejected because the physician is not enrolled, a physician must resubmit the claims after he or she is enrolled in the Medicare program in compliance with Medicare's provision for timely filing (§ 424.44).

Comment: One commenter recommended that we not require the submission of the Electronic Funds Transfer Authorization Agreement (EFT) form (CMS–588) if a provider or supplier is already receiving payments electronically.

Response: We agree with this commenter. We believe an enrolled provider or supplier who is already receiving Medicare payments electronically is not required to submit the CMS–588 with a change in enrollment unless the provider or supplier is seeking to change its depository information.

Comment: Several commenters recommended that we address concerns regarding operational issues associated with the requirement to obtain payments electronically. Specifically, these commenters recommended that we address in this final rule the practice of reversing entry procedures where we may overpay the provider or supplier and then later reclaim that overpayment.

Response: We appreciate this comment and understand this concern; however, this issue is outside the scope of the proposed rule.

Comment: Several commenters stated that the provisions of this rule eliminated a physician's right to retroactively bill for services as is the current practice for some physicians.

Response: This rule did not propose a change in the current provisions regarding retroactive billing; therefore, we believe this comment is outside the scope of the proposed rule.

Comment: Several commenters supported our proposal to reduce from 60 to 30 days for information required to process an enrollment application, and they wanted to know if they could retroactively apply the provision to pending inventories.

Response: We appreciate the support for our proposal to reduce the time allotted to produce the necessary documentation to process enrollment applications from 60 days to 30 days before allowing a contractor to reject an enrollment application. However, we will prohibit our contractors from retroactively applying this change to pending inventories. Accordingly, any applications received after the effective date of this final rule will be subject to its provisions.

Comment: Several commenters recommended that we not reduce the amount of time providers or suppliers have to respond to a request from Medicare FFS contractor, (that is, carrier, FI, or MAC) for additional information from 60 days to 30 days as proposed in § 425.525(a)(2).

Response: We continue to believe that it is essential that providers and suppliers submit a complete application, including all supporting documentation, at the time of filing or at a minimum, respond to a contractor's request for information in a timely manner. Accordingly, absent the submission of a complete application, we believe that it is appropriate that providers and suppliers respond to a contractor's request for additional information in a timely manner. We believe that allowing a provider or supplier 30 days is more than enough time to obtain and submit the requested information or documentation. Finally, we believe that this change will lead to processing efficiencies for not only the Medicare program but also for those providers and suppliers who seek to enroll or make a change in their existing Medicare enrollment information.

Comment: One commenter requested that we clarify our requirement for furnishing requested enrollment documentation with respect to the 30-day timeframe before the rejection of an enrollment application.

Response: We believe that a contractor may reject the provider or supplier's enrollment application if the provider or supplier fails to respond to a request for information in a complete and timely manner (that is, within 30 days of the contractor request for additional information.)

For example, assume that an applicant submits an enrollment application on May 1, 2008. While processing the enrollment application the contractor determines that the applicant did not complete section 3 of the application and did not submit the required supporting documentation to receive payments electronically. On May 16, 2008, the contractor notifies the applicant about the missing documentation. Assuming that the applicant does not submit all requested information by June 15, 2008 (that is, 30 days from the contractor request), the contractor may reject the application.

Comment: Several commenters stated that the proposed enrollment application processing timeframes stated in proposed § 405.874(h) were too long and would inhibit suppliers from enrolling or re-enrolling in the Medicare Program.

Response: We are also concerned about delays associated with the enrollment process. However, we recognize that many of the delays are the result of providers and suppliers not submitting a complete application at the time of filing or failing to submit complete and timely responses to a contractor's request for information.

In addition, we believe that it is appropriate to establish meaningful Medicare contractor processing timeliness standards and, as necessary, update or revise processing standards through the manual instructions and through contracts with Medicare contractors. Finally, while this final rule establishes an outer boundary for processing enrollment application, we fully expect that most enrollment applications will be processed in accordance with CMS processing requirements found in Publication 100–8, Chapter 10 of the Program Integrity Manual (PIM). The PIM establishes processing standards for initial applications, changes of information, and reassignments that all Medicare contractors must follow. Specifically, we currently require Medicare contractors to process 80 percent of initial applications within 60 days, 90 percent of initial applications within 120 days, and 99 percent of initial applications within 180 days. We also require Medicare contractors to process 80 percent of changes of information and reassignments within 45 days, 90 percent of changes of information and reassignments within 60 days and 99 percent of such applications within 90 calendar days of receipt.

With the implementation of the Provider Enrollment, Chain and Ownership System (PECOS) Web, an Internet version of the Medicare enrollment process, in FY 2008, we have established more stringent contractor processing timeliness standards for applications for enrollment submitted via PECOS Web. On January 4, 2008, we revised the processing requirements in Publication 100–8, Section 2, Chapter 10 of the PIM to establish the following processing requirements for PECOS Web applications:

Specifically, we will require Medicare contractors to process 90 percent of initial applications within 45 days, 95 percent of initial applications within 60 days, and 99 percent of initial applications within 90 days. We also require Medicare contractors to process 80 percent of changes of information and reassignments within 45 days, 90 percent of changes of information and reassignments within 60 days and 99 percent of such applications within 90 calendar days of receipt.

Since PECOS Web will improve the accuracy of applications submitted to contractors and reduce the time necessary to receive, verify and make a final determination regarding an enrollment action, we believe that the public should benefit from these processing efficiencies. Accordingly, we maintain that establishing a separate processing time standard for applications submitted via PECOS Web is appropriate.

Comment: Several commenters raised concerns as to whether we will be changing the processing standards to non-tiered percentages for processing initial applications (including revalidations), as well as with regard to changes of information (including reassignments not submitted in conjunction with an initial enrollment package).

Response: While we will maintain a tiered system we are establishing an outer boundary for the number of days for processing Medicare enrollment applications in this final rule, we will maintain more specific processing standards in Chapter 10 of the PIM.

Comment: One commenter asked if the proposed regulation will change the processing standard found in Section 2 of Chapter 10 of the PIM.

Response: This final rule does not change the provider enrollment

processing standards found in Section 2 of Chapter 10 of the PIM.

Comment: One commenter agreed with the 30-day timeframe for submitting supporting information as long as our contractors are required to follow this same timeframe for processing enrollment applications.

Response: While we are proposing an outside limit of 180 days for processing applications, we have established shorter processing timeframes in manual guidance which must be adhered to by CMS contractors. However, we believe that 30 days does not provide contractors with sufficient time to process all enrollment applications. While we believe in holding contractors responsible for meeting our defined processing standards, it is essential that providers and suppliers submit a complete application at the time of filing in order to lessen processing timeframes.

Comment: One commenter asked for clarifications as to whether the 90-day timeframe requirement for change of information and reassignment of payment requests submitted applies to both fiscal intermediaries, as well as carriers.

Response: The 90-day processing standard applies to changes in information submitted to a fiscal intermediary/MAC or a change of information or reassignment submitted to a carrier/MAC. Therefore, § 405.874(h)(3) applies to both providers and suppliers. We note that DMEPOS suppliers are required to submit changes in information to the NSC within 30 days of the changes as specified in § 424.57(c)(2).

Comment: One commenter recommended that we allow academic medical centers to submit enrollment applications at least 6 months in advance of a physician's start date.

Response: By submitting a complete enrollment application and all supporting documentation at the time of filing, a physician can efficiently enroll in the Medicare program. Additionally, with the implementation of PECOS Web, we believe that physicians will be able to enroll in a more efficient manner. Finally, since we require our contractors to verify the information provided in the enrollment application, and this cannot be accomplished if the physician is not yet working at the academic medical center, we are not able to adopt this recommendation.

Comment: One commenter suggested that the 180-day processing time for enrollment decisions was not workable for providers undergoing a change of ownership (CHOW) as specified in § 489.18.

Response: Since Medicare contractors can only process applications that are complete at the time of filing and have the necessary supporting documentation, it is essential that CHOWs are complete when submitted. When completed applications are submitted, Medicare contractors will encounter fewer obstacles in processing an application. While we are establishing an outside processing timeframe in this rule, we have established more stringent processing requirements in the manual. We recognize the importance of processing CHOWs in a timely manner and will continue to establish processing standards in the manual which seek to ensure continuity of payment.

Comment: While several commenters offered support for our proposal in § 424.535 to preclude provider or supplier billing for a period of 3 years after Medicare billing privileges are revoked, several commenters stated that a 3-year ban is too long.

Response: We agree that Medicare contractors should consider the reason associated with revocation before determining whether the contractor should establish a re-enrollment bar for a provider or supplier. The goal of the re-enrollment bar is to ensure that Medicare billing privileges are given to trustworthy providers and suppliers. Consequently, if a Medicare contractor determines that a provider's or supplier's Medicare billing privileges should be revoked, then we believe that establishing an enrollment bar is appropriate. We will provide contractors with guidance on the establishment of an enrollment bar via manual instructions. With this guidance, we believe that the contractor has discretion to establish a re-enrollment bar from 1 to 3 years depending on the severity of the basis for revocation. For example, failure to respond to revalidation request may warrant a 1-year ban whereas failure to report an adverse legal action that could preclude payment would warrant a 3-year ban.

In addition, if a contractor makes a decision to revoke Medicare billing privileges, we believe that the duration of the re-enrollment bar should not be less than 1 year. Finally, while we believe that providers and suppliers can appeal the revocation determination, we do not believe that providers and suppliers can appeal the duration of the re-enrollment bar for Medicare billing privilege. We also believe that providers and suppliers have an obligation to maintain their billing privileges and to report changes that would preclude enrollment or continued enrollment in accordance with § 410.33(g), § 424.57(c)(2), and § 424.520(b). In addition, we believe that establishing a re-enrollment bar for Medicare billing privileges that have been revoked will help protect the Medicare Trust Funds, and beneficiaries from potentially unqualified providers and suppliers.

Comment: One commenter stated that the 3-year waiting period in proposed § 424.502 was a punitive action and is not within our legal authority, and that only the OIG has been granted legal authority to exclude individuals and entities from the Medicare program.

Response: We believe that we have the obligation to protect the Medicare Trust Funds when billing privileges are revoked. We believe providers and suppliers whose billing privileges are revoked should be prevented from immediately re-entering the program. Accordingly, we believe that establishing a re-enrollment bar is appropriate and within our authority. Unlike OIG exclusions which apply government-wide and which generally last for 5 years or longer, the re-enrollment bar only applies to those billing the Medicare program.

Comment: Several commenters recommended that we do not revoke a physician's billing privileges for 3 years because the physician did not respond to a revalidation request.

Response: In the April 21, 2006 final rule, providers and suppliers learned about our intent to begin a revalidation process. Specifically, § 424.515 states that a provider or supplier (other than a DMEPOS supplier), must resubmit and recertify the accuracy of its enrollment information every 5 years. Therefore, providers and suppliers that enrolled in the Medicare program prior to 2003, but who have not completed a Medicare enrollment application since then, have had more than 2 years to come into voluntary compliance with our enrollment criteria by submitting a complete enrollment application. With this final rule, we are again notifying physicians, providers, and suppliers that they may voluntarily complete and submit a Medicare enrollment application and the necessary supporting documentation prior to our formal request for revalidation. Accordingly, providers and suppliers who choose not to come into voluntary compliance or fail to respond to a revalidation request in a complete and timely manner fail to satisfy our enrollment criteria and may be subject to revocation of their billing privileges.

Comment: Several commenters recommended that we allow providers and suppliers to participate in the Medicare program if their revocation is

successfully overturned at a higher level of appeal.

Response: Section 405.874(d)(3) states a provider or supplier's billing privileges will be reinstated back to the date that their revocation became effective if it was reversed at a higher level of appeal.

Comment: Several commenters recommended that we clarify that the period of provider or supplier ineligibility be linked to the date on which the supplier had provided a service to a beneficiary and not the date that a claim would be received or processed by a carrier.

Response: We are clarifying that this is our intent. Revocation actions concerning provider and supplier ineligibility are based upon the date on which the provider or supplier had furnished a service to a beneficiary and not the date that a claim was received or processed by a carrier or MAC.

For example, if a provider submits a claim for services provided on June 22, 2007, and the beneficiary dies on June 23, 2007, but the claim for the June 22, 2007 services was not received until August 1, 2007, if any action is taken regarding this claim, it would be with regard to the June 22, 2007 date.

Comment: One commenter suggested that there are several instances where the date of service being billed could actually be the day after the date of death and that an honest billing of the service could be perceived as fraud, and therefore cause a provider or supplier to be incorrectly revoked.

Response: We understand that there are certain situations when the date of service may legitimately be the day after the date of death of the beneficiary. Accordingly, Medicare contractors and CMS will review the specific details associated with each claim before taking any revocation action.

Comment: We received several comments regarding implementation of the proposed changes to be set forth at § 424.535(a)(8) which allows Medicare contractors to revoke Medicare billing privileges when a provider or supplier submits a claim or claims for services that could not have been furnished to a beneficiary, where the commenter believed there was not enough guidance given to the contractors to filter these claims which could cause overburdened contractors to implement this policy too widely.

Response: CMS, not a Medicare contractor, will make the determination for revocation under the authority at § 424.535(a)(8). We will direct contractors to use this basis of revocation after identifying providers or suppliers that have these billing issues. We have found numerous examples of situations where a physician claims to have furnished a service to a beneficiary more than a month after their recorded death, or when the provider or supplier was out of State when the supposed services had been furnished. In these instances, the provider has billed the Medicare program for services which were not provided and has submitted Medicare claims for service to a beneficiary who could not have received the service which was billed. This revocation authority is not intended to be used for isolated occurrences or accidental billing errors. Rather, this basis for revocation is directed at providers and suppliers who are engaging in a pattern of improper billing.

In making a revocation determination under § 424.535(a)(8), we will make the revocation determination based upon information presented by a Medicare contractor, a CMS Regional Office, or one of our Program Integrity field offices. We believe that it is both appropriate and necessary that we have the ability to revoke billing privileges when services could not have been furnished by a provider or supplier. We recognize the impact that this revocation has, and a revocation will not be issued unless sufficient evidence demonstrates abusive billing patterns. Accordingly, we will not revoke billing privileges under § 424.535(a)(8) unless there are multiple instances, at least three, where abusive billing practices have taken place. Furthermore, providers and suppliers may appeal a contractor revocation using the process outlined in part 498 if they believe that they were unduly revoked. In conclusion, we believe that providers and suppliers are responsible for the claims they submit or the claims submitted on their behalf. We believe that it is essential that providers and suppliers take the necessary steps to ensure they are billing appropriately for services furnished to Medicare beneficiaries.

Comment: Several commenters believed that contractors would be issuing revocations based upon the submission of claims for services that could not be delivered.

Response: As stated above, we will instruct Medicare contractors to issue a revocation under § 424.535(a)(8).

Comment: One commenter suggested several procedural changes regarding the processing of enrollment applications; such as, withdrawing an application and reopening a closed enrollment decision, be included in this regulation as opposed to our original procedural proposals.

Response: As outlined in § 424.510, the current enrollment application procedures allow providers and suppliers a clear means to complete and submit enrollment applications with the necessary documentation to participate in the Medicare program. Prospective providers or suppliers are responsible for obtaining the necessary documentation that demonstrates that they meet the program requirements for their provider or supplier type. If a provider or supplier cannot supply the necessary documentation at the time of filing or in response to a contractor request, then the contractor is required to reject their application and the prospective provider or supplier must begin the enrollment process anew. Finally, a prospective provider or supplier may withdraw their Medicare enrollment application at any time by informing the designated contractor in writing of the withdrawal of the application. A withdrawal request must be made by the applicant or the Authorized Official as defined in § 424.502 and in the Medicare enrollment application (CMS–855).

Unlike the claims appeals process where minor errors and omissions can be resolved though the reopening process in an effective and efficient manner, the issues involved in Provider Enrollment denials and revocations do not readily lend themselves to the reopening process. Accordingly, we have not adopted a reopening procedure in this final rule.

Comment: One commenter recommended that we revise our 2002 ''Do Not Forward'' policy because of the change in processing timeframes for enrollment applications.

Response: We believe this issue is outside the scope of the proposed rule and can not be addressed in this final rule.

Comment: One commenter recommended that if we make a change in the Medicare enrollment application that we use the processing guidelines in effect at the time of the postmark date so that the application will be treated as submitted prior to the implementation date.

Response: If we make a change in the Medicare enrollment application in the future, we will establish a transition period between the use of the prior version of the application and the new version of the application.

Comment: One commenter stated that electronic funds transfer (EFT) should be developed in concert with the CMS–855 transaction standard to ensure that there is a clear connection between the two files.

Response: We believe this issue is outside the scope of the proposed rule and can not be addressed in this final rule.

Comment: One commenter urged us to clarify that the reassignment exception still exists with regard to EFT which currently exempts individuals reassigning their benefits to a group practice from the EFT requirement.

Response: Individuals reassigning all of their benefits to a group practice are still exempt from the EFT requirement. We will update its manuals to state that only individuals and organizations receiving payments directly must receive them through EFT.

Comment: One commenter suggested that we consult with hospital-based faculty practices to determine the best way to implement EFT in this particular setting.

Response: We will continue to conduct outreach efforts to ensure that all providers and suppliers are informed about EFT policies.

Comment: One commenter recommended that adequate notification and education be provided to all who have chosen or are required to accept funds via EFT.

Response: We will continue to conduct outreach efforts to ensure that all providers and suppliers are informed about EFT policies. We believe this issue is outside the scope of the proposed rule and can not be addressed in this final rule.

Comment: One commenter recommended that notice of precertification completion be provided to group practices prior to the payment of funds via EFT.

Response: We believe this issue is outside the scope of the proposed rule and can not be addressed in this final rule.

Comment: One commenter stated we should not terminate a provider agreement when billing privileges are revoked.

Response: In the April 21, 2006 final rule, we stated in § 424.545(a) that the termination of both the provider agreement and billing privileges will happen concurrently. Accordingly, we believe that a provider cannot retain a provider agreement if its billing privileges have been revoked.

Comment: One commenter suggested that we amend the definition of supplier because they believed that the term ambulance service provider may not include suppliers of ambulance services.

Response: While we are not adopting this recommendation, we clarify in section IV. of this final rule (Provisions of the Final Regulation) that an ambulance service provider includes all providers and suppliers of ambulance services.

Comment: One commenter recommended that we conduct increased outreach and education efforts for providers, suppliers and contractor enrollment staff.

Response: We will undertake the necessary steps to ensure that our contractors understand these new provisions and apply them consistently. In addition to publishing this final rule, we will issue operational guidance to our Medicare contractors.

IV. Provisions of the Final Regulation

Based on public comments, we are adopting the provisions of the proposed rule as final with the following changes: We are amending the provisions of this final rule to apply to all providers and suppliers, including DMEPOS suppliers.

In § 405.802, we have added a definition of prospective provider.

In § 405.874(a), we amended the proposed language and adopted the provision that if a carrier, fiscal intermediary, National Supplier Clearinghouse (NSC) or MAC denies a provider's or supplier's enrollment application, then the carrier, fiscal intermediary, NSC or MAC must notify the provider or supplier by mail. The notice must include the following: (1) The reason for denial in sufficient detail to allow the provider or supplier to understand the nature of its deficiencies; (2) the right to appeal in accordance with part 498; and (3) the address to which the written appeal must be mailed.

In § 405.874(b)(1), we adopted the provision which clarified that if CMS or a CMS contractor, (that is, a carrier, fiscal intermediary, NSC or MAC) revokes a provider's or supplier's Medicare billing privileges, then CMS or its contractor must notify the provider or supplier by mail and that the notice must include—(1) The reason for the revocation in sufficient detail for the provider or supplier to understand the nature of its deficiencies; (2) the right to appeal in accordance with part 498 of this chapter; (3) the address to which the written appeal must be mailed.

In § 405.874(b)(2), we adopted the provision to separate the procedures in existing § 405.874(a) and § 405.874(b). In addition, we adopted the provision clarifying that a revocation of provider's or supplier's billing privileges that is based on a Federal exclusion or debarment is effective with the effective date of the exclusion or debarment. Moreover, if CMS or a CMS contractor revokes Medicare billing privileges, then we would not revoke an individual or organization's National Provider Identifier (NPI).

In § 405.874(b)(3), we modified our proposed provision to clarify that providers and suppliers are not paid for items or services furnished after the effective date of revocation. We removed proposed § 405.874(b)(3)(i) because it was not applicable to revocation of billing privileges. Concerning DMEPOS suppliers, section 1834(j)(1) of the Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items and supplies unless the supplier has active Medicare billing privileges. We also adopted the provision that claims submitted to carriers, fiscal intermediaries, NSC or MACs for items or services furnished during a period of provider or supplier ineligibility are to be rejected by the carrier or fiscal intermediary and not denied.

In § 405.874(c)(1), we adopted the provision that a provider's or supplier's appeal rights would follow the processes detailed in part 498. Generally denials or revocations issued by a fiscal intermediary would be handled by a CMS regional office (RO), and denials and revocations by carriers, including the NSC, would be handled by a carrier hearing officer. In those cases where a MAC issues a denial or revocation, the reconsideration would be handled by the CMS RO or a contractor hearing officer depending upon the provider or supplier type. The CMS RO's will generally be handling the Medicare Part A reconsiderations and the contractor hearing officer will generally be handling the Medicare Part B reconsiderations.

In § 405.874(d), we adopted the revisions to this section to reflect that claims for services furnished to Medicare beneficiaries during a period in which the provider's or supplier's billing privileges were not effective are rejected and not denied. If a provider or supplier is determined not to have qualified for billing privileges in one period but qualified in another, contractors process claims for services furnished to beneficiaries during the period for which the provider or supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for the recovery of overpayments. The appeals process for denied claims should not apply if a provider or supplier does not have billing privileges.

In § 405.874(d)(3), we adopted the provision that when revocation of a provider's or supplier's billing privileges are reversed upon appeal, the

provider's or supplier's billing privileges are reinstated back to the date that the revocation became effective.

In § 405.874(d)(4), we adopted the provision that if a denial of a provider's or supplier's billing privileges is reversed upon appeal, then the appeal decision establishes the date that the provider's or supplier's billing privileges will become effective.

In § 405.874(e), we adopted the provision that if a provider or supplier completes a corrective action plan and provides sufficient evidence to the carrier, fiscal intermediary, NSC or MAC that it has complied fully with the Medicare requirements, the carrier, fiscal intermediary or MAC may reinstate the supplier's billing privileges.

In § 405.874(f) we adopted the provision changing the effective date for DMEPOS supplier's billing privileges. If the NSC, NSC hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in § 424.57 of this chapter and any other requirements that may apply (for example, reinstatement after an OIG exclusion), the determination establishes the effective date of the billing privileges as not earlier than the date the carrier made the determination to deny the supplier's enrollment application. Claims are rejected for services furnished before that effective date.

In § 405.874(g), we adopted the provision that a provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed, or in having its billing privileges reinstated, may submit claims to the CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims.

In § 424.510(d)(2)(iv), we adopted the provision that at the time of enrollment, an enrollment change request or revalidation, including reenrollment of DMEPOS suppliers, providers and suppliers shall submit the CMS–588 form to receive payments via electronic funds transfer (EFT) if they are not already receiving payments via EFT.

Consistent with the authority under 31 U.S.C. 3332(f)(1), all Federal payments, including Medicare payments to providers and suppliers, shall be made by electronic funds transfer (EFT). Further, under 31 U.S.C. 3332(g), each recipient of Federal payments required to be made by electronic funds transfer shall designate 1 or more financial institutions or other authorized agents to which the payments shall be made and provide the information to CMS. While the statutory provisions at 31 CFR part 208 govern the Department of Treasury, they apply to all Federal government agencies.

Consequently, we want to clarify that the EFT requirement applies to providers and suppliers enrolling in the Medicare program or making changes to enrollment. We are requiring EFT payments for the following: (1) Providers and suppliers initially enrolling in the Medicare program; (2) providers and suppliers submitting a CMS–855 change request who are not currently receiving payments via EFT; (3) provider and suppliers responding to a revalidation or DMEPOS re-enrollment request; and (4) when CMS changes a Medicare contractor for a State or contracting jurisdiction and the provider or supplier was already receiving payments via EFT. We believe that providers and suppliers already receiving payments via EFT should continue to receive payments via EFT when CMS changes a Medicare contractor for a State or contracting jurisdiction. We believe that requiring providers and suppliers who were already receiving Medicare payments via EFT prior to a change in Medicare contractors is consistent with the provisions of the proposed rule and does not impose a consequential burden on these providers and suppliers. In addition, we believe an enrolled provider or supplier who is already receiving Medicare payments electronically is not required to submit the CMS–588 with a change in enrollment unless the provider or supplier is seeking to change its depository information. Finally, we will continue to encourage all providers and suppliers to switch to EFT payments voluntarily.

In § 424.545(a), we adopted the following provisions:

- Redesignated the first sentence of current paragraph (a) as the introductory text and revised that text to remove the reference to part 405 subpart H.
- Redesignated the second sentence of current paragraph (a) as paragraph (a)(1)(i).
- Added paragraph (a)(1)(ii) to clarify that if a provider or supplier appeals both of these sanctions, then both matters will be resolved using a single appeals process.
- Redesignated the last sentence of current paragraph (a) as paragraph (a)(2).

In § 405.874(h), we adopted the provision that established deadlines for the processing of provider enrollment actions. We adopted the provision that contractors will process initial determinations and revalidations within 180 days of receipt and that carriers, fiscal intermediaries or MACs process change-of-information and reassignment of payment requests within 90 days of receipt.

In § 424.525(a)(1) and (a)(2), we adopted the provisions that state the reasons for rejecting enrollment applications by reducing the amount of time that a provider or supplier must furnish complete information requested by a contractor from 60 to 30 days. Additionally, we adopted the provision for a reduction from 60 to 30 days for the period allowed to furnish all supporting documentation for submitting their enrollment application. In this final rule, we are also making conforming changes in paragraph (b) of this section (that is, changing 60 days to 30 days).

In § 424.535(a)(8), we adopted the provision that allows Medicare FFS contractors to revoke Medicare billing privileges when instructed to do so by CMS when a provider or supplier submits a claim or claims for services that could not have been furnished to a beneficiary. We have found numerous examples of situations where a physician or other practitioner has billed for services furnished to beneficiaries that are undeliverable, including but not limited to situations where the beneficiary was deceased, the directing physician or beneficiary was not in the State or country when services were furnished, or when the beneficiary was in another setting where these services could not be administered, or the equipment necessary for testing was not present where the testing is said to have occurred.

We believe that this new revocation authority is consistent with the other types of revocations already used by CMS and its contractors under § 424.535. Further, providers and suppliers may appeal a contractor revocation using the process outlined in part 498.

This basis for revocation is essential to the efficient operation of the Medicare program, because it will enable us to take an important step in protecting the expenditure of public monies for service providers whose motive and billing practices are questionable, at best, and at worst, of a sort that might prompt an aggressive response from the law enforcement community. We also want to alert providers and suppliers that we may be proposing other provisions related to revocation of providers and suppliers in the calendar year 2009 physician fee schedule proposed rule.

In § 424.535(b)(2), we adopted the provision to establish a re-enrollment bar of not less than 1 year and not greater than 3 years when a provider or supplier's Medicare billing privileges are revoked. Specifically, we adopted the provision that when a provider or supplier, including all authorized officials, delegated officials and practitioners, is revoked for any of the reasons listed at § 424.535, that the provider, supplier, delegated official or authorizing official be prohibited from enrolling in the Medicare program for a period of not less than 1 year but not greater than 3 years. While we have adopted a provision to establish a re-enrollment bar for 1 year but not greater than 3 years, this enrollment bar does not preclude CMS or its contractor from denying re-enrollment if a provider or supplier was convicted of felony within the preceding 10-year period as described in § 424.530(a)(3) or is not in compliance with any other enrollment criteria.

In § 498.1(g), we adopted the provision for an ALJ hearing, and judicial review for any provider or supplier whose application for enrollment or reenrollment in Medicare has been denied or whose billing privileges have been revoked.

In § 498.2—

- Finalizing our definition of a ''supplier'' to include the following: (1) A supplier of DMEPOS; ambulance service provider; independent diagnostic testing facility; physician; and other practitioner such as physician assistant; and (2) remove the reference to ''prospective supplier.'' To further clarify the provisions applicable to providers and suppliers, we have added the definition of provider and prospective provider to § 405.802. We also note that we made technical edits to the definitions of supplier in § 405.802 and § 498.2.
- Revised the definition of provider to (1) remove the reference to prospective provider; and (2) make technical changes. These technical changes include correcting the term ''hospital transplant center'' to read ''hospital, transplant center'' and removing the phrase ''that has in effect an agreement to participate in Medicare''.
- Added new definitions for ''prospective supplier,'' ''prospective provider,'' largely based upon comments received. Since applicants (prospective provider and suppliers) who are not enrolled in the Medicare program, still are afforded appeal rights based on an enrollment denial, we maintain that it is important to clarify that any prospective applicant (provider or supplier) is afforded appeal rights through this process.

We also adopted the provision to remove the definition of the ''Office of Hearings and Appeals (OHA)'' because the function of this office has been moved from the Social Security Administration to the DHHS. Additionally, we adopted the provision that revised the definition of ''affected party'' to specify that it includes CMS or a CMS contractor.

In § 498.5, we adopted the provision that revised this section by adding a new paragraph (l) to clarify the administrative process that would be used by a prospective provider, existing provider, prospective supplier or existing supplier dissatisfied with an initial determination or revised initial determination related to the denial or revocation of Medicare billing privileges.

In § 498.5(f)(2), we adopted the provision to be consistent with the change in § 498.1(g). This implements the mandate of section 936(a)(2) of the MMA regarding judicial review. We have adopted these standards because the FFS contractors need sufficient time to adjudicate the facts and make a reasoned Medicare enrollment decision. Moreover, while we established an outside limit for processing these applications, the vast majority of these decisions are made within 120 days.

In § 498.22(a), we adopted the provision to add that we have delegated authority to our contractors to reconsider an initial determination. We also are adopting the provision to revise § 498.22(b)(1) to state that a reconsideration request is to be filed with CMS or with the State survey agency, or, in the case of prospective suppliers, the entity specified in the notice of initial determination. Additionally, we adopted the provision at § 498.44 to remove the term ''Associate Commissioner for Hearings and Appeals,'' and we have replaced it with the term ''Secretary,'' because this function is no longer under the Social Security Administration; it is now under the DHHS.

In § 405.874(c)(2), we adopted the provision which clarifies that a provider or supplier is required to prove that it is in compliance with all Medicare requirements for billing privileges, and that the Medicare FFS contractor incorrectly denied or revoked the supplier's billing privileges. At § 498.56, we added a new paragraph (e) that specifies the ''good cause'' exception to the admission of new evidence at the ALJ level of appeal.

In § 498.78(a), we adopted the proposal to delete the provision that an affected party concur in writing or on the record with a CMS or OIG request for remand. We contend that the appeals process is enhanced by allowing an ALJ to remand a provider enrollment case to the Medicare FFS contractor when CMS requests a remand. Further, we believe that a remand request could result in either a favorable decision to the appellant or in the administrative record being complete.

In § 498.79, we adopted the provision that when a request for an ALJ hearing is filed after CMS or a FFS contractor has denied an enrollment application, that an ALJ must issue a decision, dismissal order or remand to CMS, as appropriate, no later than 180 days after the initial request for a hearing.

We revised § 498.86 to prohibit providers and suppliers from submitting new provider enrollment issues or evidence at the DAB level of review.

Finally, in § 498.88(g), we adopted the provision that when a request for a Board review is filed after an ALJ has issued a decision or dismissal order, that the Board must issue a decision, dismissal order or remand to the ALJ, as appropriate, no later than 180 days after the appeal was received by the Board.

V. 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 comments 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; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. However, we believe the information collection activities referenced in § 405.874 are exempt under the terms of the PRA for the following reasons:
- As defined in 5 CFR 1320.4(a)(2), information collections conducted or sponsored during the conduct of criminal or civil action, or during the conduct of an administrative action, investigation, or audit involving an

agency against specific individuals or entities are exempt from the PRA.

- As described in 5 CFR 1320.3(h)(9), facts or opinions obtained or solicited through nonstandardized follow-up questions designed to clarify responses to approved collections, are exempt from the PRA; and
- Nonstandardized information collections directed to less than 10 persons do not constitute information collections as outlined in 5 CFR 1320.3(c)(4).

We believe that the collection requirements are part of the administrative process, and collected in a nonstandardized manner. Since each case will be different, based on the reasons for denial or revocation, and evidence presented, they fall under these exceptions.

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: William Parham, CMS–6003–F, 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.: Carolyn Lovett, CMS Desk Officer, CMS–6003–F, *carolyn_lovett@omb.eop.gov*. Fax (202) 395–6974.

VI. Regulatory Impact Statement

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, 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 (U.S.C. 804(s)).

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 does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief for 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 $6.5 to $31.5 million in any one 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 rule will not have a significant economic impact on a substantial number of small entities.

We maintain that this final rule would not have an adverse impact on small entities; in fact, it would afford small suppliers a measure of protection against adverse actions by us, and extend protection to a larger group of suppliers beyond the DMEPOS suppliers currently covered under § 405.874. Because this final rule would merely clarify, expand, and update our current policy and administrative appeal rights, we anticipate slight, if any, economic impact on small entities.

According to data submitted to us by carriers in calendar year 2003, approximately 166,500 enrollment applications were submitted to the Medicare carriers by suppliers seeking to receive billing privileges. We believe that a vast majority of these applicants were small businesses. Of those applications, approximately 2,000 were denied, and approximately 200 applicants requested a reconsideration. Because we have already granted appeal rights to the affected suppliers via instructions to carriers, we estimate that this regulation would have minimal impact on carrier workloads.

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 final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. There is no negative impact on the program or on small businesses.

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 $120 million. This rule does not mandate expenditures by either the governments mentioned or the private sector, therefore no analysis is required.

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 regulation was reviewed by the Office of Management and Budget.

Lists 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 424

Emergency medical services, Health facilities, Health professions, Medicare Reporting and recordkeeping requirements.

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 amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for Part 405, subpart H, continues to read as follows:

Authority: Sections 1102, 1842(b)(3)(C), 1869(b), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b) and 1395hh).

Subpart H—Appeals Under the Medicare Part B Program

■ 2. Section 405.802 is amended by adding the definitions of ''provider'', ''prospective provider'', ''prospective supplier'' and ''supplier'' in alphabetical order to read as follows:

§ 405.802 Definitions.

* * * * *

Prospective provider means any of the entities specified in the definition of provider under § 498.2 of this chapter that seeks to be approved for coverage of its services by Medicare.

Prospective supplier means any of the listed entities specified in the definition of supplier specified in this section that seeks to be approved for coverage of its services under Medicare.

Provider means either of the following:

(1) Any of the following entities that have in effect an agreement to participate in Medicare:

(i) Hospital.

(ii) Transplant center.

(iii) Critical access hospital (CAH).

(iv) Skilled nursing facility (SNF).

(v) Comprehensive outpatient rehabilitation facility (CORF).

(vi) Home health agency (HHA).

(vii) Hospice.

(viii) Religious nonmedical health care institution (RNHCI).

(2) Any of the following entities that have in effect an agreement to participate in Medicare but only to furnish outpatient physical therapy or outpatient speech pathology services.

(i) Clinic.

(ii) Rehabilitation agency.

(iii) Public health agency.

* * * * *

Supplier means any of the following entities:

(1) An independent laboratory.

(2) Supplier of durable medical equipment Prosthetics, orthotics, or supplies (DMEPOS).

(3) Ambulance service provider.

(4) Independent diagnostic testing facility.

(5) Physician or other practitioner such as physician assistant.

(6) Physical therapist in independent practice.

(7) Clinical laboratories.

(8) Supplier of portable X-ray services.

(9) Rural health clinic (RHC).

(10) Federally qualified health center (FQHC).

(11) Ambulatory surgical center (ASC).

(12) An entity approved by CMS to furnish outpatient diabetes self-management training.

(13) End-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services.

* * * * *

■ 3. Section 405.874 is revised to read as follows:

§ 405.874 Appeals of CMS or a CMS contractor.

A CMS contractor's (that is, a carrier, Fiscal Intermediary or Medicare Administrative Contractor (MAC)) determination that a provider or supplier fails to meet the requirements for Medicare billing privileges.

(a) *Denial of a provider or supplier enrollment application.* If CMS or a CMS contractor denies a provider's or supplier's enrollment application, CMS or the CMS contractor must notify the provider or supplier by certified mail. The notice must include the following:

(1) The reason for the denial in sufficient detail to allow the provider or supplier to understand the nature of its deficiencies.

(2) The right to appeal in accordance with part 498 of this chapter.

(3) The address to which the written appeal must be mailed.

(b) *Revocation of Medicare billing privileges—*

(1) *Notice of revocation.* If CMS or a CMS contractor revokes a provider's or supplier's Medicare billing privileges, CMS or a CMS contractor must notify the supplier by certified mail. The notice must include the following:

(i) The reason for the revocation in sufficient detail for the provider or supplier to understand the nature of its deficiencies.

(ii) The right to appeal in accordance with part 498 of this chapter.

(iii) The address to which the written appeal must be mailed.

(2) *Effective date of revocation.* The revocation of a provider's or supplier's billing privileges is effective 30 days after CMS or the CMS contractor mails the notice of its determination to the provider or supplier. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment.

(3) *Payment after revocation.* Medicare does not pay and the CMS contractor rejects claims for services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

(c) *Appeal rights.* (1) A provider or supplier may appeal the initial determination to deny a provider or supplier's enrollment application, or if applicable, to revoke current billing privileges by following the procedures specified in part 498 of this chapter.

(2) The reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges will be handled by a CMS Regional Office or a contractor hearing officer not involved in the initial determination.

(3) Providers and suppliers have the opportunity to submit evidence related to the enrollment action. Providers and suppliers must, at the time of their request, submit all evidence that they want to be considered.

(4) If supporting evidence is not submitted with the appeal request, the contractor contacts the provider or supplier to try to obtain the evidence.

(5) If the provider or supplier fails to submit this evidence before the contractor issues its decision, the provider or supplier is precluded from introducing new evidence at higher levels of the appeals process.

(d) *Impact of reversal of contractor determinations on claims processing.*

(1) Claims for services furnished to Medicare beneficiaries during a period in which the supplier billing privileges were not effective are rejected.

(2) If a supplier is determined not to have qualified for billing privileges in one period but qualified in another, Medicare contractors process claims for services furnished to beneficiaries during the period for which the supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for the recovery of overpayments.

(3) If a revocation of a supplier's billing privilege is reversed upon appeal, the supplier's billing privileges are reinstated back to the date that the revocation became effective.

(4) If the denial of a supplier's billing privileges is reversed upon appeal and becomes binding, then the appeal decision establishes the date that the supplier's billing privileges become effective.

(e) *Reinstatement of provider or supplier billing privileges following corrective action.* If a provider or supplier completes a corrective action plan and provides sufficient evidence to the CMS contractor that it has complied fully with the Medicare requirements, the CMS contractor may reinstate the provider's or supplier's billing privileges. The CMS contractor may pay for services furnished on or after the effective date of the reinstatement. The effective date is based on the date the provider or supplier is in compliance with all Medicare requirements. A CMS contractor's refusal to reinstate a supplier's billing privileges based on a corrective action plan is not an initial determination under part 498 of this chapter.

(f) *Effective date for DMEPOS supplier's billing privileges.* If a CMS contractor, contractor hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in § 424.57 of this chapter and any other requirements that may apply, the determination establishes the effective date of the billing privileges as not earlier than the date the carrier made

the determination to deny the DMEPOS supplier's enrollment application. Claims are rejected for services furnished before that effective date.

(g) *Submission of claims.* A provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed in a binding decision, or in having its billing privileges reinstated, may submit claims to the CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims. If the claims previously were filed timely but were rejected, they are considered filed timely upon resubmission. Previously denied claims for items or services rendered during a period of denial or revocation may be resubmitted to CMS within 1 year after the date of reinstatement or reversal.

(h) *Deadline for processing provider enrollment initial determinations.* Contractors approve or deny complete provider or supplier enrollment applications to approval or denial within the following timeframes:

(1) *Initial enrollments.* Contractors process new enrollment applications within 180 days of receipt.

(2) *Revalidation of existing enrollments.* Contractors process revalidations within 180 days of receipt.

(3) *Change-of-information and reassignment of payment request.* Contractors process change-of-information and reassignment of payment requests within 90 days of receipt.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 4. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. Section 424.510 is amended by adding new paragraphs (d)(2)(iv) and (e) to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(d) * * *

(2) * * *

(iv) At the time of enrollment, an enrollment change request, revalidation or change of Medicare contractors where the provider or supplier was already receiving payments via EFT, providers and suppliers must agree to receive Medicare payments via EFT, if not already receiving payment through EFT. In order to receive Medicare payments via EFT, providers and suppliers must submit the CMS–588 form.

* * * * *

(e) Providers and suppliers must—

(1) Agree to receive Medicare payment via electronic funds transfer (EFT) at the time of enrollment, revalidation, change of Medicare contractors where the provider or supplier was already receiving payments via EFT or submission of an enrollment change request; and

(2) Submit the CMS–588 form to receive Medicare payment via electronic funds transfer.

■ 6. Section 424.525 is amended by—

■ A. Republishing paragraph (a) introductory text.

■ B. Revising paragraphs (a)(1), (a)(2) and (b).

The revisions read as follows:

§ 424.525 Rejection of a provider or supplier's enrollment application for Medicare enrollment.

(a) *Reasons for rejection.* CMS contractors may reject a prospective provider's or supplier's enrollment application for the following reasons:

(1) The prospective provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the contractor request for the missing information.

(2) The prospective provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.

(b) *Extension of 30-day period.* CMS, at its discretion, may choose to extend the 30 day period if CMS determines that the prospective provider or supplier is actively working with CMS to resolve any outstanding issues.

* * * * *

■ 7. Section 424.535 is amended by—

■ A. Adding a new paragraph (a)(8).

■ B. Redesignating paragraphs (c) through (f) as (d) through (g).

■ C. Adding a new paragraph (c).

The addition and revision read as follows:

§ 424.535 Revocation of enrollment and billing privileges from the Medicare program.

(a) * * *.

(8) *Abuse of billing privileges.* The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

(b) * * *

(c) *Reapplying after revocation.* After a provider, supplier, delegated official, or authorizing official has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation.

* * * * *

■ 8. Section 424.545 is amended by revising paragraph (a) to read as follows:

§ 424.545 Provider and supplier appeal rights.

(a) *General.* A prospective provider or supplier that is denied enrollment in the Medicare program, or a provider or supplier whose Medicare enrollment has been revoked may appeal CMS' decision in accordance with part 498, subpart A of this chapter.

(1) *Appeals resulting in the termination of a provider agreement.* (i) When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS' decision in accordance with part 498 of this chapter with the final decision of the appeal applying to both the billing privileges and the provider agreement.

(ii) When a provider appeals the revocation of billing privileges and the termination of its provider agreement, there will be one appeals process which will address both matters. The appeal procedures for revocation of Medicare billing privileges will apply.

(2) *Payment of unpaid claims.* Payment is not made during the appeals process. If the provider or supplier is successful in overturning a denial or revocation, unpaid claims for services furnished during the overturned period may be resubmitted.

* * * * *

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

■ 9. 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

■ 10. Section 498.1 is amended by revising paragraph (g) to read as follows:

§ 498.1 Statutory basis.

* * * * *

(g) Section 1866(j) of the Act provides for a hearing and judicial review for any provider or supplier whose application for enrollment or reenrollment in Medicare is denied or whose billing privileges are revoked.

* * * * *

■ 11. Section 498.2 is amended by—
■ A. Revising the definition of ''affected party''.
■ B. Removing the definition of ''OHA''.
■ C. Adding the definitions of ''prospective provider'' and ''prospective supplier''.
■ D. Revising the definitions of ''provider'' and ''supplier''.

The addition and revisions read as follows:

§ 498.2 Definitions.

* * * * *

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate. For provider or supplier enrollment appeals, an affected party includes CMS or a CMS contractor.

* * * * *

Prospective provider means any of the entities specified in the definition of provider under this section that seeks to be approved for coverage of its services by Medicare or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

Prospective supplier means any of the listed entities specified in the definition of supplier in this section that seek to be approved for coverage of its services by Medicare.

Provider means either of the following:

(1) Any of the following entities that have in effect an agreement to participate in Medicare:

(i) Hospital.

(ii) Transplant center.

(iii) Critical access hospital (CAH).

(iv) Skilled nursing facility (SNF).

(v) Comprehensive outpatient rehabilitation facility (CORF).

(vi) Home health agency (HHA).

(vii) Hospice.

(viii) Religious nonmedical health care institution (RNHCI).

(2) Any of the following entities that have in effect an agreement to participate in Medicare but only to furnish outpatient physical therapy or outpatient speech pathology services.

(i) Clinic.

(ii) Rehabilitation agency.

(iii) Public health agency.

Supplier means any of the following entities that have in effect an agreement to participate in Medicare:

(1) An independent laboratory.

(2) Supplier of durable medical equipment prosthetics, orthotics, or supplies (DMEPOS).

(3) Ambulance service provider.

(4) Independent diagnostic testing facility.

(5) Physician or other practitioner such as physician assistant.

(6) Physical therapist in independent practice.

(7) Supplier of portable X-ray services.

(8) Rural health clinic (RHC).

(9) Federally qualified health center (FQHC).

(10) Ambulatory surgical center (ASC).

(11) An entity approved by CMS to furnish outpatient diabetes self-management training.

(12) End-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services.

■ 12. Section 498.5 is amended by—
■ A. Revising paragraph (f)(2).
■ B. Adding a new paragraph (l).

The revision and addition read as follows:

§ 498.5 Appeal rights.

* * * * *

(f) * * *

(2) A supplier or prospective supplier dissatisfied with an ALJ decision may request Board review, and has a right to seek judicial review of the Board's decision.

* * * * *

(l) *Appeal rights related to provider enrollment.*

(1) Any prospective provider, an existing provider, prospective supplier or existing supplier dissatisfied with an initial determination or revised initial determination related to the denial or revocation of Medicare billing privileges may request reconsideration in accordance with § 498.22(a).

(2) CMS, a CMS contractor, any prospective provider, an existing provider, prospective supplier, or existing supplier dissatisfied with a reconsidered determination under paragraph (l)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(3) CMS, a CMS contractor, any prospective provider, an existing provider, prospective supplier, or existing supplier dissatisfied with a hearing decision may request Board review, and any prospective provider, an existing provider, prospective supplier, or existing supplier has a right to seek judicial review of the Board's decision.

Subpart B—Initial, Reconsidered, and Revised Determinations

■ 13. Section 498.22 is amended by revising paragraphs (a) and (b)(1) to read as follows:

§ 498.22 Reconsideration.

(a) *Right to reconsideration.* CMS or one of its contractors reconsiders an initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section. For denial or revocation of enrollment, prospective providers and suppliers and providers and suppliers have a right to reconsideration.

(b) * * *

(1) With CMS or with the State survey agency, or in the case of prospective supplier the entity specified in the notice of initial determination;

* * * * *

Subpart D—Hearings

■ 14. Section 498.40 is amended by revising paragraph (a)(1) to read as follows:

§ 498.40 Request for hearing.

(a) * * *

(1) An affected party entitled to a hearing under § 498.5 may file a request for a hearing with the ALJ office identified in the determination letter.

* * * * *

■ 15. Section 498.44 is revised to read as follows:

§ 498.44 Designation of hearing official.

(a) The Secretary or his or her delegate designates an ALJ or a member or members of the Board to conduct hearings.

(b) If appropriate, the Secretary or the delegate may designate another ALJ or another member or other members of the Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes any ALJ of the Department of

Health and Human Services or members of the Board who are designated to conduct a hearing.

■ 16. Section 498.56 is amended by—

■ A. Revising paragraph (a)(2).

■ B. Adding a new paragraph (e).

The revision and addition read as follows:

§ 498.56 Hearing on new issues.

* * * * *

(a) * * *

(2) Except for provider or supplier enrollment appeals which are addressed in § 498.56(e), the ALJ may consider new issues even if CMS or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after the prehearing conference.

* * * * *

(e) *Provider and supplier enrollment appeals: Good cause requirement.* (1) *Examination of any new documentary evidence.* After a hearing is requested but before it is held, the ALJ will examine any new documentary evidence submitted to the ALJ by a provider or supplier to determine whether the provider or supplier has good cause for submitting the evidence for the first time at the ALJ level.

(2) *Determining if good cause exists.*

(i) *If good cause exists.* If the ALJ finds that there is good cause for submitting new documentary evidence for the first time at the ALJ level, the ALJ must include evidence and may consider it in reaching a decision.

(ii) *If good cause does not exist.* If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(2) *Notification to all parties.* As soon as possible, but no later than the start of the hearing, the ALJ must notify all parties of any evidence that is excluded from the hearing.

■ 17. Section 498.78 is amended by revising paragraph (a) to read as follows:

§ 498.78 Remand by the Administrative Law Judge.

(a) If CMS requests a remand, the ALJ may remand any case properly before him or her to CMS.

* * * * *

■ 18. A new § 498.79 is added to subpart D to read as follows:

§ 498.79 Timeframes for deciding an enrollment appeal before an ALJ.

When a request for an ALJ hearing is filed after CMS or a FFS contractor has denied an enrollment application, the ALJ must issue a decision, dismissal order or remand to CMS, as appropriate, no later than the end of the 180-day period beginning from the date the appeal was filed with an ALJ.

Subpart E—Departmental Appeals Board Review

■ 19. Section 498.86 is amended by revising paragraph (a) to read as follows:

§ 498.86 Evidence admissible on review.

(a) Except for provider or supplier enrollment appeals, the Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing (or the documents considered by the ALJ if the hearing was waived) if the Board considers that the additional evidence is relevant and material to an issue before it.

* * * * *

■ 20. Section 498.88 is amended by adding a new paragraph (g) to read as follows:

§ 498.88 Decision or remand by the Departmental Appeals Board.

* * * * *

(g) When a request for Board review of a denial of an enrollment application is filed after an ALJ has issued a decision or dismissal order, the Board must issue a decision, dismissal order or remand to the ALJ, as appropriate, no later than 180 days after the appeal was received by the Board.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: November 16, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: *March 17, 2008.*

Michael O. Leavitt,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 406, 407, and 408

[CMS–4129–F]

RIN 0938–AO77

Medicare Program; Special Enrollment Period and Medicare Premium Changes

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule provides a special enrollment period (SEP) for Medicare Part B and premium Part A for certain individuals who are sponsored by prescribed organizations as volunteers outside of the United States and who have health insurance that covers them while outside the United States. Under the SEP provision, qualifying volunteers can delay enrollment in Part B and premium Part A, or terminate such coverage, for the period of service outside of the United States and reenroll without incurring a premium surcharge for late enrollment or reenrollment.

This final rule also codifies provisions that require certain beneficiaries to pay an income-related monthly adjustment amount (IRMAA) in addition to the standard Medicare Part B premium, plus any applicable increase for late enrollment or reenrollment. The income-related monthly adjustment amount is to be paid by beneficiaries who have a modified adjusted gross income that exceeds certain threshold amounts. It also represents the amount of decreases in the Medicare Part B premium subsidy, that is, the amount of the Federal government's contribution to the Federal Supplementary Medicare Insurance (SMI) Trust Fund.

DATES: *Effective Date:* These regulations are effective on August 26, 2008.

FOR FURTHER INFORMATION CONTACT: Denise Cox, (410) 786–3195.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Medicare is a Federal health insurance program that helps millions of Americans pay for health care. Beneficiaries include eligible individuals age 65 or older and certain people younger than age 65 who also qualify to receive Medicare. These individuals include those who have

disabilities and those who have permanent kidney failure (end-stage renal disease).

Medicare Parts A and B are the subject of this final rule. Hospital insurance (Part A) helps to pay for inpatient care in hospitals, skilled nursing facilities, as well as home health care and hospice care. Part B or supplementary medical insurance (SMI) helps to pay for physicians' services, outpatient hospital services, durable medical equipment, and a number of other medical services and supplies that are not covered under Part A.

Part A is financed primarily through compulsory payroll taxes under the Federal Insurance Contributions Act (FICA). Individuals age 65 or over who are entitled to receive Social Security or railroad retirement benefits, or who are eligible for Social Security benefits and have filed an application for hospital insurance, are entitled to receive Part A benefits without paying a monthly premium. However, individuals who do not qualify for premium-free Part A, may voluntarily enroll in Part A but are required to pay a monthly premium. These individuals generally include those who have not worked 10 years in Medicare-covered employment or are not the spouse, divorced spouse or widow(er) of an individual who has worked 10 years in Medicare-covered employment. In addition, they must meet the following requirements: (1) Be at least age 65; (2) a resident of the United States; (3) a United States citizen or an alien who has been lawfully admitted for permanent residence and who has resided continuously in the United States for the 5-year period immediately preceding the month of enrollment; (4) not otherwise eligible to receive Part A benefits without having to pay a premium; and (5) entitled to Part B or are eligible and have enrolled.

Enrollment in Part B is open to all persons who are entitled to Part A benefits, as well as to persons who are not entitled to Part A benefits, provided certain requirements are satisfied. Part B is financed primarily through premiums paid by or on behalf of beneficiaries, along with transfers made from the General Fund of the Treasury. Section 1839(a) of the Social Security Act (the Act) requires the Secretary of Health and Human Services to determine the Medicare Part B standard monthly premium amount annually. Currently, the standard monthly premium represents approximately 25 percent of the estimated total Part B program cost for aged enrollees. The remaining 75 percent of the total estimated cost is subsidized by the Federal government through transfers to the Federal SMI Trust Fund from the General Fund of the Treasury.

Individuals who do not enroll in Part B or premium Part A when first eligible or who enroll and later terminate their coverage may only enroll during the general enrollment period, which is January through March of each year, unless an exception applies. The coverage will be effective the following July 1. Under section 1839(b) of the Act, individuals who delay enrolling in premium Part A or Part B for 12 or more months must pay a premium surcharge.

B. General Enrollment Period Exceptions

1. Special Enrollment Period (SEP)

Currently, section 1837(i) of the Act provides a special enrollment period (SEP) for individuals age 65 or over who are working or who are the spouses of working individuals who are covered under a group health plan (GHP). For disabled individuals, who are under age 65, the SEP applies if the individual is covered by a GHP by reason of the current employment status of the individual or the individual's spouse, or if the individual is covered by a large group health plan (LGHP) by reason of the current employment status of the individual or a member of the individual's family. In this type of situation, enrollment in Part B can take place anytime the individual is covered under the GHP or LGHP based on current employment status or during the 8-month period that begins the first full month after the GHP or LGHP coverage ends. Because section 1818(c) of the Act provides that the enrollment provisions in section 1837 (except subsection (f) thereof) apply to persons authorized to enroll in premium Part A, we have extended this SEP to premium Part A enrollments.

2. Transfer Enrollment Period (TEP)

Another exception is the transfer enrollment period (TEP) for enrollment in premium Part A. The TEP is for individuals age 65 or older who are otherwise eligible to enroll in premium Part A; are enrolled in a plan with an organization listed in section 1876 of the Act; and whose coverage under the plan is terminated for any reason. Here, an individual may enroll in premium Part A beginning any month that the individual is enrolled in the plan, and ending with the last day of the 8-month period following the last month in which the individual is no longer enrolled in the plan.

3. Statutory Changes

Section 5115(a)(2) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) amended section 1837 of the Act to add a new subsection (k), which provides a SEP for certain international volunteers. Beginning January 1, 2007, a SEP for Part B is provided to qualifying international volunteers who are eligible to enroll in Part B because they meet the requirements in section 1836(1) or (2) of the Act, but who do not enroll in Part B during the initial enrollment period or who terminate enrollment during a month in which they qualify as an international volunteer. Enrollment can take place during the 6-month period beginning on the first day of the month which includes the date the individual no longer qualifies under this provision. Coverage for an individual who enrolls during a SEP in accordance with this provision begins on the first day of the month following the month in which the individual enrolls.

Under new section 1837(k)(3) of the Act, an individual qualifies as an international volunteer if he or she is serving in a program outside of the United States that covers at least a 12-month period, and that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (the Code) and exempt from taxation under section 501(a) of the same Code. The individual must also have health insurance coverage to cover medical services while serving overseas in the program. Specifically, qualifying organizations under section 501(c)(3) of the Code that are exempt from taxation under section 501(a) of the Code are ''corporations, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals. * * *'' Furthermore, to qualify for this exemption, no part of the net earnings of the organization can inure to the benefit of any private shareholder or individual and no substantial part of the activities can be used for propaganda, or otherwise attempt to influence legislation (except as otherwise provided in section 510(h) of the Code) or participate or intervene (including the publishing or distributing of statements) in political campaigns on behalf of (or in opposition to) any candidate for public office.

C. Income-Related Monthly Adjustment Amount Under Medicare Part B

Section 811 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amends section 1839 of the Act and establishes a Medicare Part B premium subsidy reduction referred to as the ''Income-Related Monthly Adjustment Amount'' (IRMAA). Section 1839(i) of the Act requires that an income-related monthly adjustment amount be added to a beneficiary's Part B premium if his or her modified adjusted gross income exceeds the established threshold amounts. The IRMAA reduces the amount that the beneficiary's premium is subsidized by the Federal government. All beneficiaries will continue to receive some subsidy of their premium.

Section 1839(i) of the Act establishes a sliding scale that will be used to establish four income-related monthly adjustment amounts that will increase a beneficiary's Medicare Part B premium by specific percentages. If a beneficiary's modified adjusted gross income is greater than the statutory threshold amounts, the beneficiary will pay a larger portion of the estimated total cost of Part B coverage. The 2007 income ranges, as set forth in section 1839(i)(3)(C)(i) of the Act, started at $80,000 for a beneficiary filing an individual tax return, and $160,000 for a beneficiary filing a joint income tax return, and are listed in the following table:

Individual tax filers with income:	Joint tax filers with income:	Premium percentage
Greater than $80,000 and less than or equal to $100,000	Greater than $160,000 and less than or equal to $200,000	35
Greater than $100,000 and less than or equal to $150,000	Greater than $200,000 and less than or equal to $300,000	50
Greater than $150,000 and less than or equal to $200,000	Greater than $300,000 and less than or equal to $400,000	65
Greater than $200,000	Greater than $400,000	80

In calendar year (CY) 2007, individual tax filers with income less than or equal to $80,000 and joint tax filers with income less than or equal to $160,000 will continue to pay the standard premium which represents roughly 25 percent of the estimated total Part B program costs. As specified in section 1839(i)(5) of the Act, each dollar amount in this table would be adjusted annually based on the Consumer Price Index.

Section 811 of the MMA also provided for a 5-year phase-in of the Medicare Part B premium subsidy reduction. However, section 1839(i) was subsequently amended by section 5111 of the DRA to provide for a 3-year phase-in period. Therefore, the percentages presented in this table reflect the Part B premium percentages that certain beneficiaries will pay once IRMAA is fully phased-in.

The ''hold-harmless'' provision in section 1839(f) of the Act provides for a reduction to the Part B premium for beneficiaries whose Social Security or Railroad Board (RRB) annuity cost of living adjustments (COLAs) are not sufficient to cover the Part B premium increase. If in a given year, the increase in the Part B premium would cause an individual's Social Security or RRB check to be less than it was the year before, the premium is reduced to ensure that the amount of the individual's Social Security benefit (or RRB annuity) stays the same. To be held harmless, a beneficiary must have had the Part B premium deducted from both the December check of the prior year and the January check of the next year. Under section 1839(f) of the Act, the ''hold-harmless'' provision does not apply to beneficiaries who are required to pay an IRMAA based on their modified adjusted gross income. These beneficiaries must pay the full Medicare Part B standard monthly premium, plus any applicable penalty for late enrollment or reenrollment, plus the income-related monthly adjustment amount.

Section 702(a)(5) of the Act allows SSA to make the rules and regulations necessary or appropriate to carry out the functions of SSA. Other provisions in section 811 of the MMA provide SSA with additional specific authorization to make rules and regulations to determine which beneficiaries are required to pay the different income-related monthly adjustment amounts.

In the October 27, 2006 **Federal Register** (71 FR 62923), SSA issued a final rule establishing regulations governing the determination of income-related monthly adjustment amounts. This final rule explains: (1) The statutory requirement to implement an income-related adjustment to the Part B premium subsidy; (2) the information that would be used to determine whether a beneficiary must pay an income-related monthly adjusted amount and the amount of any adjustment; (3) when SSA will consider a major life-changing event that results in a significant reduction in a beneficiary's modified adjusted gross income; and (4) how a beneficiary can appeal SSA's determination about the beneficiary's income-related monthly adjustment amount. For a more detailed discussion see SSA's October 27, 2006 final rule (71 FR 62923).

II. Provisions of the Proposed Regulation and Analysis of and Responses to Public Comments

We received four timely public comments in response to the Special Enrollment Period and Medicare Premium Changes proposed rule published in the September 28, 2007 **Federal Register**. In this section of the final rule, we address all comments received regarding the provisions of our proposed rule.

We proposed to add a new § 406.25, which would allow certain individuals who are sponsored by prescribed organizations as volunteers outside of the United States and have health care insurance to qualify for a SEP for premium hospital insurance (Part A). We recognize that section 5115 of the DRA, in amending section 1839(b) of the Act, explicitly provides only for a SEP for Part B, which we have provided for in new § 407.21. However, since section 1818(c) of the Act applies all of the provisions of section 1837 of the Act (except subsection (f) thereof) to persons authorized to enroll under section 1818 of the Act, we believe that the SEP provided in section 5115 of the DRA also applies to enrollment in premium Part A.

Comment: Three commenters expressed concern that although § 406.25 of the September 2007 proposed rule tracks the language of section 5115 of the DRA, § 407.21 is not worded exactly the same as § 406.25 and could be interpreted as imposing different standards. Specifically, they believe that the requirements of § 406.25 (''an individual [that] is serving as a volunteer outside the United States through a program that covers at least a 12-month period'') and the requirement of § 407.21 (''if while serving as a volunteer outside of the United States the individual is in a program that covers a 12-month period of service outside of the United States'') are two different standards.

The commenters also note that there is a slight difference between the wordings in the preamble for these two sections. They believe that § 406.25 and § 407.21 should be substantively identical.

Response: To ensure that the SEP standards are interpreted consistently, we are revising the regulation text of § 406.25 and § 407.21.

In § 406.33(a)(3), we proposed to make a technical correction by removing an incorrect phrase ''the 7-month special enrollment period under § 406.21(e)'' and replacing it with the phrase ''the special enrollment period under § 406.24.'' We did not receive any public comment on this proposal and are adopting the provision with only a technical change, as discussed further in this section.

In § 406.33(a)(5) and (6), we proposed to exclude from the calculation of the premium surcharge those months the individual qualifies for the SEP described in § 406.25(a). We did not receive any public comment on this proposal and are adopting the provision with technical changes, as discussed further in this section.

We proposed to add a new § 407.21, which implements section 5115 of the DRA by allowing certain individuals who are sponsored by prescribed organizations as volunteers outside of the United States and have health care insurance that covers medical services while serving overseas to qualify for a Medicare Part B SEP.

Comment: Two commenters noted that section 5115 of the DRA requires that volunteers serve in a program that covers at least a 12-month period, as opposed to requiring that their actual service outside the country last for at least 12 months. These commenters stated that, under rare, unforeseeable circumstances, a volunteer in a program that covers at least a 12-month period may be required to return to the United States in less than 12 months. They believe that these volunteers should qualify for the SEP provided by section 5115 of the DRA.

Response: We agree and have revised § 407.21 to clarify that the volunteer has to serve in a program that covers at least a 12-month period.

In § 408.20 (e)(3)(iii), we proposed to implement section 811(b)(1)(C) of the MMA by excluding from the ''hold harmless'' provision (known as the ''nonstandard premium'') individuals who are required to pay the income-related monthly adjustment amount (IRMAA). Such beneficiaries must pay the full Medicare Part B standard monthly premium plus any applicable premium surcharge for late enrollment or re-enrollment, plus the income-related monthly adjustment amount. We did not receive any public comment on this proposal and are adopting the provision as proposed.

In § 408.24(a)(10), we proposed to implement section 5115(a) of the DRA by excluding from the calculation of the premium surcharge those months the individual meets the requirements of proposed § 407.21. We also proposed to make a conforming change in § 408.24 (b)(2)(i) of this section by revising the cross-reference to include the new paragraph § 408.24(a)(10). We did not receive any public comment on these proposals and are adopting the provisions as proposed.

Finally, we proposed to add a new § 408.28 to specify that, beginning January 1, 2007, Medicare beneficiaries will be informed that they may be required to pay an income-related monthly adjustment amount in addition to the standard Part B premium, plus any applicable increase for late enrollment or reenrollment, if their modified adjusted gross income exceeds the threshold limits specified in 20 CFR 418.1115. We did not receive any public comment on this proposal and are adopting the provision as proposed.

After review and analysis of public comment, we are also making the following technical changes in this final rule:

- In § 406.33(a)(3), the cross-reference ''§ 406.24 of this part'' is revised to read ''§ 406.24 of this subpart''.
- In § 406.33(a)(5), the cross-reference ''§ 406.25 of this subpart'' is revised to read ''for a SEP under 406.25(a) of this subpart''.
- In § 406.33(a)(6), the cross-reference ''§ 406.25(b) of this part'' is revised to read ''§ 406.25(b) of this subpart''.
- In § 407.21(b), the cross-reference ''paragraph (b) of this section'' is revised to read ''paragraph (a) of this section''.

Lastly, we are making a technical change to the section heading for § 406.24 to clarify that the special enrollment period relates to coverage under group health plans.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Related to Special Enrollment Period for Volunteers Outside the United States (§ 406.25)

Section 406.25 outlines the requirements that an individual volunteer must meet to qualify for a SEP. A qualifying individual can enroll or reenroll without incurring a surcharge for a late enrollment or reenrollment. Specifically, § 406.25(a)(1) and (2) state that an individual volunteer must demonstrate that his or her volunteer service is through a program that covers at least a 12-month period and is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of the Internal Revenue Code.

The burden associated with this requirement is the time and effort associated with verifying that the volunteer was in a 12-month program and demonstrating the tax-exempt status of the organization sponsoring the individual. The estimated burden associated with this requirement is 15 minutes per individual. We estimate that 1,500 individuals will be subject to this requirement on a yearly basis for a total annual burden of 375 burden hours.

In addition, § 406.25(a)(3) requires that an individual demonstrate that he or she has health insurance that covers medical services received outside of the United States during his or her period of service. The burden associated with this requirement is the time and effort associated with demonstrating possession of health insurance coverage that covers the medical services received outside of the United States. We estimate the burden for verifying coverage to be 15 minutes per individual; we also estimate that 1,500 individuals will be subject to this requirement on a yearly basis. The total

estimated burden is 375 annual burden hours.

B. ICRs Related to Special Enrollment Period for Volunteers Outside the United States (§ 407.21)

Section 407.21 addresses the provision of a SEP for an individual who elects not to enroll or to be deemed enrolled in SMI when first eligible and an individual who terminates SMI enrollment. To be eligible for the SEP, the individual must meet the criteria outlined in the regulations text. As stated in § 407.21(a), the individual must: (1) Serve as a volunteer in a program that covers at least a 12-month period of service; (2) be a volunteer in a program sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under 501(a) of such Code; and (3) be able to demonstrate that he or she had health insurance coverage that covers medical services received outside of the United States during his or her period of service.

The burden associated with the requirements in § 407.21(a)(1) and (2) is the time and effort associated with verifying that the volunteer was in a 12-month program, and demonstrating the tax-exempt status of the organization sponsoring the individual, and submitting the information to CMS. The burden associated with these requirements is discussed in detail in the explanation of the burden for § 406.25.

The burden associated with the § 407.21(a)(3) is the time and effort associated with an individual demonstrating that he or she has health insurance that covers medical services received outside of the United States during his or her period of service. The burden associated with this requirement is discussed in detail in the explanation of the burden for § 406.25.

TABLE A.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
§ 406.25(a)(1 and 2) and § 407.21(a)(1 and 2).	0938–New	1500	1500	.25	375
§ 406.25(a)(3) and § 407.21(a)(3)	0938–New	1500	1500	.25	375
Total					750

We have submitted a copy of this final rule to OMB for its review of the information collection requirements contained in this section. In addition, we are seeking OMB approval for the aforementioned information collection requirements under a separate notice and comment process. These requirements are not final until they are approved by OMB.

IV. Regulatory Impact Statement

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, 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). We do not anticipate that there will be more than 1,500 beneficiaries (international volunteers) at any one time who will qualify for a SEP. To qualify under this SEP, the Medicare beneficiary must have elected not to enroll in Part B or premium Part A during the initial enrollment period, or terminated enrollment, because the individual was serving as a volunteer outside the United States. In addition, the individual must have served as a volunteer outside of the United States in a program that covers at least a 12-month period, and that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of that Code, and must have health care insurance coverage that covers medical services while serving overseas in the program. It is for this reason that we anticipate that the overall expenditure for this provision of the Medicare program projected over a 5-year period would be negligible. In addition, this rule only codifies the income-related monthly adjustment amount provision of MMA. It is for these reasons that this rule 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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million 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 rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. 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 final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed (and subsequent final rule)

that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this final rule does not impose any costs on State or local governments, therefore the requirements of E.O. 13132 are not applicable.

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 406

Health facilities, Kidney diseases, Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 408

Medicare.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

■ 1. The authority citation for part 406 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Premium Hospital Insurance

■ 2. Section 406.24 is amended by revising the section heading to read as follows:

§ 406.24 Special enrollment period related to coverage under group health plans.

* * * * *

■ 3. Section 406.25 is added to read as follows:

§ 406.25 Special enrollment period for volunteers outside the United States.

(a) *General rule.* A SEP, as defined in § 406.24(a)(4) of this subchapter, is provided for an individual that meets the following requirements:

(1) The individual is serving as a volunteer outside of the United States in a program that covers at least a 12-month period.

(2) The individual is in a program that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of Internal Revenue Code of 1986.

(3) The individual can demonstrate that he or she has health insurance that covers medical services that the individual receives outside the United States while serving in the program.

(4) The individual—

(i) At the time he or she first met the requirements of § 406.10 through 406.15 or § 406.20(b), elected not to enroll in premium hospital insurance during the individual's initial enrollment period; or

(ii) Terminated enrollment in premium hospital insurance during a month in which the individual met the requirements of this section for a SEP.

(b) *Duration of SEP.* The SEP is the 6-month period beginning on the first day of the month that includes the date that the individual no longer meets the requirements of paragraph (a) of this section.

(c) *Effective date of coverage.* Coverage under a SEP authorized by this section begins on the first day of the month following the month in which the individual enrolls.

■ 4. Section 406.33 is amended by—

■ A. Revising paragraph (a)(3).

■ B. Adding paragraphs (a)(5) and (a)(6).

The revision and additions read as follows:

§ 406.33 Determination of months to be counted for premium increase: Enrollment.

(a) * * *

(3) Any months during the SEP under § 406.24 of this subpart, during which premium hospital insurance coverage is in effect.

* * * * *

(5) For premiums due for months after December 2006, any months during which the individual met the requirements for a SEP under § 406.25(a) of this subpart.

(6) Any months during the 6-month SEP described in § 406.25(b) of this subpart during which premium hospital insurance coverage is in effect.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

■ 5. The authority citation for part 407 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Individual Enrollment and Entitlement for SMI

■ 6. Section 407.21 is added to read as follows:

§ 407.21 Special enrollment period for volunteers outside the United States.

(a) *General rule.* A SEP, as defined in § 406.24(a)(4) of this subchapter, is provided for an individual who does not elect to enroll or to be deemed enrolled in SMI when first eligible, or who terminates SMI enrollment, if the individual meets the following requirements:

(1) The individual is serving as a volunteer outside of the United States in a program that covers at least a 12-month period.

(2) The individual is in a program that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986.

(3) The individual demonstrates that he or she has health insurance that covers medical services that the individual receives outside of the United States while serving in the program.

(b) *Duration of SEP.* The SEP is the 6-month period beginning on the first day of the month that includes the date that the individual no longer satisfies the provisions of paragraph (a) of this section.

(c) *Effective date of coverage.* Coverage under a SEP authorized by this section, begins on the first day of the month following the month in which the individual enrolls.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

■ 7. The authority citation for part 408 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Amount of Monthly Premiums

■ 8. Section 408.20 is amended by adding paragraph (e)(3)(iii) to read as follows:

§ 408.20 Monthly premiums.

* * * * *

(e) * * *

(3) * * *

(iii) Beginning with CY 2007, a nonstandard premium may not be applied to individuals who are required to pay an income-related monthly adjustment amount described in § 408.28 of this part.

* * * * *

■ 9. Section 408.24 is amended by—

■ A. Adding paragraph (a)(10).

■ B. Revising paragraph (b)(2)(i).

The addition and revision read as follows:

§ 408.24 Individuals who enrolled or reenrolled before April 1, 1981 or after September 30, 1981.

(a) * * *

(10) For premiums due for months beginning with January 1, 2007, the following:

(i) Any months after December 2006 during which the individual met the conditions under § 407.21(a) of this chapter.

(ii) Any months of Part B (SMI) coverage for which the individual enrolled during a special enrollment period as provided in § 407.21(b) of this chapter.

(b) * * *

(2) * * *

(i) Any of the periods specified in paragraph (a) of this section; and

* * * * *

■ 10. Section 408.28 is added to read as follows:

§ 408.28 Increased premiums due to the income-related monthly adjustment amount (IRMAA).

Beginning January 1, 2007, Medicare beneficiaries must pay an income-related monthly adjustment amount in addition to the Part B (SMI) standard monthly premium, plus any applicable increase for late enrollment or reenrollment, if the beneficiary's modified adjusted gross income exceeds the threshold amounts specified in 20 CFR 418.1115.

(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, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 7, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–14040 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3014–F]

RIN 0938–AJ29

Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule finalizes the hospital conditions of participation requirements for hospitals that transfuse blood and blood components. It requires hospitals to: Prepare and follow written procedures for appropriate action when it is determined that blood and blood components the hospitals received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and extend the records retention period for transfusion-related data to 10 years. The intent is to aid in the prevention of HCV infection and to create opportunities for disease prevention that, in most cases, can occur many years after recipient exposure to a donor.

DATES: *Effective Date:* The interim final rule amending 42 CFR part 482 published August 24, 2007 at 72 FR 48562 and effective on February 20, 2008, is adopted as final June 27, 2008.

FOR FURTHER INFORMATION CONTACT: Mary Collins, (410) 786–3189. Marcia Newton, (410) 786–5265.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 1861(e) of the Social Security Act (the Act), hospitals must meet certain conditions in order to participate in the Medicare program. These conditions are intended to protect patient health and safety and ensure that high-quality care is provided. Hospitals receiving payment under Medicaid must meet the Medicare conditions of participation (CoPs).

The CoPs for hospital laboratory services currently specifies the steps hospitals must take when they become aware they have administered potentially human immunodeficiency virus infectious blood or blood components to a patient. All laboratories must be CLIA-certified to participate in Medicare and Medicaid. The Centers for Medicare & Medicaid Services (CMS) and Federal agencies that comprise the Public Health Services, including the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH), are responsible for ensuring the safety of blood and blood components.

Hepatitis C virus (HCV) was first discovered and established as a causative agent of transfusion-associated hepatitis in the late 1980s. In October 1989, FDA's Blood Products Advisory Committee (BPAC) first discussed steps to identify and quarantine potentially HCV infectious blood and blood components remaining in storage and notify recipients that they may possibly have received infectious blood or blood products. These steps are known as a ''lookback.'' BPAC advised that there was insufficient information available concerning HCV infection to propose either product quarantine or notification of recipients transfused with blood and blood components prepared from prior collections from donors later determined to be at increased risk for transmitting HCV.

On November 16, 2000, we published in the **Federal Register** a proposed rule (65 FR 69416). In that proposed rule, we discussed in detail the steps that had been taken since the late 1980's to avoid the transmission of HCV infection and to create opportunities for disease prevention that, in most cases, can occur many years after recipient exposure to a donor.

On August 24, 2007, we published an interim final rule with comment period in the **Federal Register** (72 FR 48562). The interim final rule with comment period incorporated the provisions of the November 16, 2000 proposed rule, responses to public comments, and changes to further conform our regulation to FDA's final rule that was also published on August 24, 2007. For a detailed discussion of this information, we refer the reader to the August 24, 2007 interim final rule (72 FR 48562 through 48565).

II. Provisions of the Interim Final Rule With Comment Period

In order to have consistent industry standards for potentially infectious blood and blood components, on August 24, 2007, we published in the **Federal Register** an interim final rule with comment period (72 FR 48562) entitled, ''Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services''. The provisions of the interim final rule were effective on February 20, 2008. The interim final rule with comment period addressed the comments CMS received regarding the proposed rule that was published on November 16, 2000 (65 FR 69416). Since our proposed rule was published in conjunction with the FDA's rule, we coordinated our responses with the FDA's responses in its ''lookback'' rule (72 FR 48766) entitled, ''Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV

Infection'' (''lookback''). In the interim final rule with comment period, we implemented the following provisions—

- Changed the reference of ''blood establishments'' to ''blood collecting establishments'' (BCE). Under this requirement, a BCE must notify a hospital if it supplies such hospital with potentially HCV infectious blood.
- Amended the hospital conditions of participation to require hospitals to develop agreements with outside BCEs under which the BCE would notify the hospital if it supplied the hospital with potentially HCV infectious blood and blood components.
- Required hospitals, when notified by BCEs, to quarantine prior collections from a donor who later tested repeatedly reactive for evidence of HCV infection, and to notify transfusion recipients of the prior collections, based on further testing of the donor, as appropriate.
- Required blood banks to notify a hospital of potentially infected blood within 3 calendar days after testing. We also require hospitals to make at least three attempts to notify the patient, or to notify the attending physician who ordered the blood or blood components.
- Required hospitals to destroy and re-label previous collection of blood or blood components held in quarantine if the results of the testing were indeterminate.
- Required hospitals to maintain adequate records of the source and disposition of all units of blood and blood components for at least 10 years after the date of disposition.

III. Analysis of and Responses to Public Comments and Provisions of the Final Regulation

We did not receive any public comments on the August 24, 2007 interim final rule with comment period. Therefore, the provisions of this final rule are identical to the provisions of the August 24, 2007 interim final rule with comment period (72 FR 48562).

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment when 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements.

Condition of Participation: Laboratory Services (§ 482.27)

Section 482.27(b)(3) requires a hospital that regularly uses the services of an outside BCE to establish and maintain a written agreement with the BCE that governs the procurement, transfer, and availability of blood and blood components. This section also requires the BCE to notify the hospital within 3 calendar days after the date on which the donor tested reactive for evidence of HCV infection or after the date on which the blood establishment was made aware of other test results indicating evidence of HCV infection, as outlined in (b)(3)(i) through (iii).

Section 482.27(b)(5) requires a hospital to maintain, in a manner that permits prompt retrieval, adequate records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition. In addition, this section requires a hospital to maintain a fully funded and documented plan that will allow the hospital to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

Section 482.27(b)(6) requires a hospital that has administered potentially HIV or HCV infectious blood or blood components (either directly through its own BCE or under an agreement), or released the blood or blood components to another entity or individual, to make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient, that potentially HIV or HCV infectious blood or blood components were transfused to the patient. Time frame and notification requirements are outlined in § 482.27(b)(6), (b)(7), and (b)(8).

Section 482.27(b)(9) requires a hospital to maintain policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records.

Section 482.27(b)(10) requires a physician or hospital, if the patient has been adjudged incompetent by a State court, to notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process for HIV infection and inform the deceased patient's legal representative or relative. If the patient is a minor, the legal guardian must be notified.

While all of the aforementioned information collection requirements referenced are subject to the Paperwork Reduction Act, the associated burden is captured and discussed in the Food and Drug Administration's (FDA) final regulation titled ''Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection'' (72 FR 48766).

The FDA's rule assigns a one-time burden of 16 hours for hospitals to develop procedures to conduct lookback activities. We also require hospitals that currently receive blood from an outside BCE to have an agreement with the BCE that governs the procurement, transfer, and availability of blood and blood components for HIV. Our rule requires hospitals to modify their current agreements to include HCV. Although the FDA does not require hospitals to have an agreement with a BCE, we believe that the time necessary to perform this task will be minimal and is already captured in the 16 hours allotted in the FDA rule.

In the interim final rule with comment period, we assigned 1 token hour of burden to these requirements; however, we are no longer assessing 1 token burden hour for the information collection requirements because, as stated earlier, the burden associated with the information collection requirements contained in this final rule was addressed in the FDA's final rule (72 FR 48766). The burden associated with the FDA's final rule was approved under OMB control number 0910–0610 with an October 31, 2010, expiration date.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 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), Executive Order 13132 on Federalism and the Congressional Review Act (5 U.S.C. 804(2)).

In the August 24, 2007 interim final rule with comment period, we presented a full regulatory impact analysis that discussed the costs and benefits of the rule. The provisions of the interim final rule with comment period became effective on February 20, 2008. For a full description of the regulatory impact analysis, we refer the reader to the August 24, 2007 interim final rule (see 72 FR 48570 through 48574). We did not receive any comments on the August 24, 2007 interim final rule with comment period; and therefore, we have not made any changes to the regulatory impact analysis in this final rule. This rule merely finalizes, without change, the interim final rule, which is already in effect. Therefore, we have determined that this final rule has no economic impact.

Executive Order 12866 (as amended) 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 must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The August 24, 2007 interim final rule with comment period estimated a one-time cost of $41.6 million and an annual cost of $1.7 million. Because the estimated cost falls below the threshold for a major rule, we have determined that this final rule is not 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 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 $31.5 million in any 1 year. For purposes of the RFA, a majority of hospitals are considered small entities due to their non-profit status. The agency has examined the impact on small entities and the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of 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 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 (superseded by ''core-based statistical areas'') and has fewer than 100 beds. As stated above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates impose spending costs on State, local, or tribal governments in the aggregate, or by private sector in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $130 million. We believe this final rule will not be an economically significant rule as described in the Executive Order, or a significant action as defined in the Unfunded Mandates Reform Act. Aggregate impacts and expenditures imposed by this final rule, will not reach $130 million for State, local, or tribal governments in the aggregate, or by the private sector.

We did not receive any comments on the August 24, 2007 interim final rule with comment period, and as previously stated above, we have not made any changes to the impact analysis in this final rule. As summarized, the impacts in the interim rule with comment period presented an overall one-time cost of $41.6 million and an annual cost of $1.7 million. The one-time cost of $41.6 million consists of $2.7 million for the development of HCV lookback procedures and $38.9 million for the historical record review (retrospective lookback effort). The annual cost of $1.7 million consists of $1.4 million for record retention (retain records for 10 years) and $0.3 million for prospective reviews.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that the rule does not contain 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. Accordingly, we have concluded that the rule does not contain policies that have Federalism implications as defined in the Executive Order 13132 and, consequently, a Federalism summary impact statement is not required.

B. Conclusion

In addition to the prospective HIV lookback that hospitals are currently required to perform, hospitals are also required to conduct a lookback of transfusion recipients of potentially HCV-infected blood. This final rule also requires hospitals to have in their agreements with BCEs, that BCEs notify hospitals after performing their own FDA-mandated lookback.

In accordance with the provisions of Executive Order 12866, this final rule was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

■ The interim final rule with comment period amending 42 CFR Part 482, which was published on August 24, 2007, in the **Federal Register** at 72 FR 48562 through 48574, is adopted as a final rule.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 25, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 22, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–13279 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–B–7791]

Withdrawal of Final Flood Elevation Determination for the District of Columbia, Washington, DC

AGENCY: Federal Emergency Management Agency (FEMA), DHS.

ACTION: Final rule; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) withdraws the final flood elevation determinations for the District of Columbia, published in the **Federal Register** on April 17, 2008, at 73 FR 20810, 20814–20815. Final flood elevation determinations will be made at a later date.

DATES: *Effective Date:* This rule is effective June 27, 2008.

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., Engineering Management Section, Mitigation Division, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3151.

SUPPLEMENTARY INFORMATION: On March 26, 2008, FEMA issued a letter to the District of Columbia (''the District'') finalizing that community's flood elevation determinations. The final flood elevation information was published in the **Federal Register** on April 17, 2008, at 73 FR 20810, 20814–20815. The March 26, 2008 letter also established September 26, 2008 as the anticipated effective date for the Flood Insurance Study (FIS) and Flood Insurance Rate Map (FIRM) for the District. Pending further consideration, the finalization of the above FIS and FIRM has been postponed. It is therefore necessary at this time to rescind the final flood elevation determinations issued to the District on March 26, 2008. Until FEMA determines that the District's FIRM can be processed, the community's final flood elevation determinations are hereby withdrawn in accordance with section 110 of the Flood Disaster Protection Act of 1973, codified at 42 U.S.C. 4104.

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. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

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 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

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 to withdraw the following:

The final flood elevation determination published at 73 FR 20810, 20814–20815, April 17, 2008 for the District of Columbia.

Dated: June 19, 2008.

Michael K. Buckley,

Deputy Assistant Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. E8–14328 Filed 6–26–08; 8:45 am]

BILLING CODE 9110–12–P

Proposed Rules

Federal Register
Vol. 73, No. 125
Friday, June 27, 2008

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0674; Directorate Identifier 2008–NM–086–AD]

RIN 2120–AA64

Airworthiness Directives; Avions Marcel Dassault-Breguet Model Falcon 10 Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) that applies to all Avions Marcel Dassault-Breguet Model Falcon 10 airplanes. The existing AD currently requires either revising the airplane flight manual (AFM) and installing a placard in the flight deck to prohibit flight into known or forecasted icing conditions, or repetitively inspecting for delamination of the flexible hoses in the wing (slat) anti-icing system and performing corrective actions if necessary. The existing AD also requires replacement of the flexible hoses installed in the slat anti-icing systems, which ends the repetitive inspections. This proposed AD would continue to require replacement of the flexible hoses installed in the slat anti-icing systems with new hoses, but at intervals defined in flight hours instead of flight cycles. This proposed AD results from information we received from operators and the airplane manufacturer indicating that the repetitive interval for the required replacement deviated from the referenced service information. We are proposing this AD to prevent collapse of the flexible hoses in the slat anti-icing system, which could lead to insufficient anti-icing capability and, if icing is encountered in this situation, could result in reduced controllability of the airplane.

DATES: We must receive comments on this proposed AD by July 28, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0674; Directorate Identifier 2008–NM–086–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On August 17, 2007, we issued AD 2007–18–08, amendment 39–15188 (72 FR 51161, September 6, 2007), for all Avions Marcel Dassault-Breguet Model Falcon 10 airplanes. That AD requires either revising the airplane flight manual (AFM) and installing a placard in the flight deck to prohibit flight into known or forecasted icing conditions, or repetitively inspecting for delamination of the flexible hoses in the wing (slat) anti-icing system and performing corrective actions if necessary. That AD also requires replacement of the flexible hoses installed in the slat anti-icing systems with new hoses, which ends the repetitive inspections. That AD resulted from a report of in-service delamination of a flexible hose in the slat anti-icing system at a time earlier than previously reported. We issued that AD to prevent collapse of the flexible hoses in the slat anti-icing system, which could lead to insufficient anti-icing capability and, if icing is encountered in this situation, could result in reduced controllability of the airplane.

Actions Since Existing AD Was Issued

Since issuance of AD 2007–18–08, we have received information from operators and the airplane manufacturer indicating that the repetitive interval for accomplishing the replacement of the flexible hoses required by paragraph (k) of that AD deviated from the referenced service information (*i.e.*, Dassault Service Bulletin F10–313, Revision 1, dated May 10, 2006). As published, paragraph (k) of AD 2007–11–07 reads ''* * * Repeat the hose replacement at intervals not to exceed 700 flight cycles.'' The term ''flight cycles'' is incorrect. We inadvertently used the term ''flight cycles'' instead of ''flight hours'' in this sentence. Therefore, we have determined that additional rulemaking is necessary to revise the repetitive interval for replacing the flexible hoses from 700 flight cycles to 700 flight hours.

Existing Relevant Service Information

Dassault has previously issued Service Bulletin F10–313, Revision 1, dated May 10, 2006. The service bulletin describes procedures for replacing the flexible hoses installed in the slat anti-icing system with new hoses. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The EASA mandated the service information and issued EASA airworthiness directive 2006–0114, dated May 10, 2006, to ensure the continued airworthiness of these airplanes in the European Union.

FAA's Determination and Requirements of the Proposed AD

These airplanes are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. As described in FAA Order 8100.14A, ''Interim Procedures for Working with the European Community on Airworthiness Certification and Continued Airworthiness,'' dated August 12, 2005, the EASA has kept the FAA informed of the situation described above. We have examined the EASA's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States.

This proposed AD would supersede AD 2007–18–08 and would continue to require replacement of the flexible hoses installed in the slat anti-icing systems with new hoses, but at new repetitive intervals. This proposed AD would require accomplishing the actions specified in service bulletin described previously.

Change to Existing AD

This proposed AD would retain certain requirements of AD 2007–18–08. As a result, the corresponding paragraph identifiers have changed in this proposed AD, as listed in the following table:

REVISED PARAGRAPH IDENTIFIERS

Requirement in AD 2007–18–08	Corresponding requirement in this proposed AD
paragraph (k)	paragraph (f).
paragraph (l)	paragraph (g).

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Hose replacement	8	$880	$1,520 per replacement cycle.	Up to 146	Up to $221,920, per replacement cycle.

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

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. 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, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–15188 (72 FR 51161, September 6, 2007) and adding the following new airworthiness directive (AD):

Avions Marcel Dassault-Breguet Aviation (AMD/BA): Docket No. FAA–2008–0674; Directorate Identifier 2008–NM–086–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by July 28, 2008.

Affected ADs

(b) This AD supersedes AD 2007–18–08.

Applicability

(c) This AD applies to all Avions Marcel Dassault-Breguet Model Falcon 10 airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from information we received from operators and the airplane manufacturer indicating that the repetitive interval for the required replacement deviated from the referenced service information. We are issuing this AD to prevent collapse of the flexible hoses in the slat anti-icing system, which could lead to insufficient anti-icing capability and, if icing is encountered in this situation, could result in reduced controllability of the airplane.

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.

Certain Requirements of AD 2007–18–08

Hose Replacement

(f) Within 330 flight hours or 7 months after October 11, 2007 (the effective date of AD 2007–18–08), whichever occurs first: Replace the flexible hoses installed in the slat anti-icing system with new hoses having part number (P/N) FAL1007, in accordance with the Accomplishment Instructions of Dassault Service Bulletin F10–313, Revision 1, dated May 10, 2006. Repeat the hose replacement thereafter at intervals not to exceed 700 flight cycles, except as provided by paragraph (h) of this AD.

(g) Replacement of a hose before October 11, 2007, in accordance with Dassault Service Bulletin F10–313, dated August 10, 2005, is acceptable for compliance with the requirements of paragraph (f) of this AD.

New Requirements of This AD

New Repetitive Interval

(h) As of the effective date of this AD, repeat the hose replacement required by paragraph (f) of this AD within 700 flight hours since the last replacement, or within 100 flight hours after the effective date of this AD, whichever occurs later, and thereafter at intervals not to exceed 700 flight hours.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, International Branch, ANM–116, FAA, ATTN: Tom Rodriguez, Aerospace Engineer, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Related Information

(j) European Aviation Safety Agency airworthiness directive 2006–0114, dated May 10, 2006, also addresses the subject of this AD.

Issued in Renton, Washington, on June 8, 2008.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–14575 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–143453–05]

RIN 1545–BE96

Capital Costs Incurred To Comply With EPA Sulfur Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

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

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations under section 179B of the Internal Revenue Code (Code) relating to the deduction for qualified capital costs paid or incurred by a small business refiner to comply with the highway diesel fuel sulfur control requirements of the Environmental Protection Agency (EPA). The temporary regulations implement changes to the law made by the American Jobs Creation Act of 2004, the Energy Policy Act of 2005, and the Tax Technical Corrections Act of 2007. The text of those temporary regulations also serves as the text of these proposed regulations. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by September 25, 2008. Outlines of topics to be discussed at the public hearing scheduled for October 28, 2008, at 10 a.m. must be received by September 22, 2008.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–143453–05), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–143453–05), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–143453–05). The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Nicole Cimino, (202) 622–3110; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Oulwafunmilayo Taylor, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR: MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by August 26, 2008. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

The collection of information in this proposed regulation is in section 1.179B–1T(d) and section 1.179B–1T(e). This information collected under section 1.179B–1T(d) relates to the election under section 179B(a) by a small business refiner to deduct a portion of the qualified capital costs paid or incurred. The information collected under section 1.179B–1T(e) relates to the election under section 179B(e) by a cooperative small business refiner to allocate all or some of its section 179B(a) deduction to its cooperative owners and to notify those cooperative owners of the allocated amount. This information will be used by the IRS for examination purposes. The collection of information is required to obtain a benefit. The likely respondents are small business refiners.

Estimated total annual reporting burden: 50 hours.

The estimated annual burden per respondent varies from .75 to 1.5 hours,

depending on individual circumstances, with an estimated average of 1 hour.

Estimated number of respondents: 50.

Estimated frequency of responses: Annually.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend 26 CFR part 1 by adding regulations under section 179B of the Code. The temporary regulations contain rules relating to the deduction provided under section 179B for qualified costs paid or incurred by a small business refiner to comply with the highway diesel fuel sulfur control requirements of the EPA. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based upon the fact, as discussed earlier in this preamble, that the amount of time necessary to record and retain the required information is estimated to average one hour for those taxpayers electing to deduct qualified capital costs and electing to allocate all or some of that deduction to certain owners. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the Treasury Department specifically request comments on the clarity of the proposed rules and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for October 28, 2008, beginning at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, all visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written or electronic comments by September 25, 2008 and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by September 22, 2008. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Nicole R. Cimino, Office of Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. Section 1.179B–1 is added to read as follows:

§ 1.179B–1 Deduction for capital costs incurred in complying with Environmental Protection Agency sulfur regulations.

[The text of this proposed § 1.179B–1 is the same as the text of § 1.179B–1T published elsewhere in this issue of the **Federal Register**].

Kevin M. Brown,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E8–14708 Filed 6–26–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–151135–07]

RIN 1545–BH39

Multiemployer Plan Funding Guidance; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of a public hearing on proposed rulemaking.

SUMMARY: This document provides notice of a public hearing on a notice of proposed rulemaking providing additional rules for certain multiemployer defined benefit plans that are in effect on July 16, 2006. These proposed regulations affect sponsors and administrators of, and participants in multiemployer plans that are in either endangered or critical status. These regulations are necessary to implement the new rules set forth in section 432 that are effective for plan years beginning after 2007. The proposed regulations reflect changes made by the Pension Protection Act of 2006.

DATES: The public hearing is being held on July 31, 2008, at 10 a.m. The IRS must receive outlines of the topics to be discussed at the hearing by July 10, 2008.

ADDRESSES: The public hearing is being held in the auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Send submissions to: CC: PA: LPD: PR (REG–151135–07), room 5203, Internal

Revenue Service, P. O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC: PA: LPD: PR (REG–151135–07), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit electronic outlines of oral comments via the Federal eRulemaking Portal at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Bruce Perlin, (202) 622–6090; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Richard A. Hurst at *Richard.A.Hurst@irscounsel.treas.gov* or (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed rulemaking (REG–151135–07) that was published in the **Federal Register** on Tuesday, March 8, 2008 (73 FR 14417).

Persons who wish to present oral comments at the hearing that submitted written comments must submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (signed original and eight (8) copies) by July 10, 2008.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing or in the Freedom of Information Reading Room (FOIA RR) (Room 1621) which is located at the 11th and Pennsylvania Avenue NW., entrance, 1111 Constitution Avenue, NW., Washington, DC.

Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E8–14563 Filed 6–26–08; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2007–0522; FRL–8686–1]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Virginia Major New Source Review for Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule

SUMMARY: EPA is proposing limited approval of a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia. This revision pertains to amendments to Virginia's existing new source review permit program for owners of sources located or locating in Nonattainment areas which were submitted to EPA on February 12, 2007. EPA is proposing limited approval of these changes to the nonattainment new source review program, because while the SIP revision submitted by the Commonwealth strengthens the SIP, it does not fully meet the current Federal requirements for the allowable lookback period under the definition of ''baseline actual emissions''. EPA is also proposing full approval of a related SIP revision submitted by the Commonwealth on December 16, 2003, pertaining to amendments made to Virginia's existing nonattainment new source review permit program at that time. This action is being taken under the Clean Air Act (CAA or the Act). In a separate action, EPA has addressed changes made by Virginia to its prevention of significant deterioration (PSD) new source review rules which were previously submitted on October 10, 2006.

DATES: Written comments must be received on or before July 28, 2008.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2007–0522 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. E-mail: campbell.dave@epa.gov.

C. *Mail:* EPA–R03–OAR–2007–0522, David Campbell, Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2007–0522. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Sharon McCauley, (215) 814–3376, or by e-mail at *mccauley.sharon@epa.gov*.

SUPPLEMENTARY INFORMATION: On December 16, 2003 and February 12, 2007, the Commonwealth of Virginia

submitted revisions to its SIP for approval of amendments to Virginia's existing new source review (NSR) permit program for owners of sources locating in nonattainment areas.

I. Background

On December 31, 2002, the U.S. EPA published revisions to the Federal PSD and nonattainment new source review (NNSR) regulations (67 FR 80186), effective March 3, 2003. These changes to the Federal NSR regulations were reconsidered with minor changes on November 7, 2003 (68 FR 63021) and collectively, these two final actions are called the ''2002 New Source Review (NSR) Reform Rules''.

The 2002 NSR Reform Rules made changes to five areas of the NSR programs. In summary, the 2002 Rules: (1) Provide a new method for determining the baseline actual emissions; (2) adopt an actual-to-projected actual methodology for determining whether a major modification has occurred; (3) allow major stationary sources to comply with plant-wide applicability limits to avoid having a significant emissions increase that triggers the requirements of the major NSR program; (4) provide a new applicability provision for emissions units that are designated clean units; and (5) exclude pollution control projects (PCPs) from the definition of ''physical change or change in the method of operation.'' The November 7, 2003 notice of final action added a definition for ''replacement unit'' and clarified an issue regarding the Plant-wide Applicability Limitation (PALs) baseline calculation procedures for newly constructed units.

On June 24, 2005, the United States Court of Appeals for the District of Columbia Circuit ruled in *New York* v. *EPA,* 413 F.3d 3 (DC Cir. June 24, 2005) that EPA lacked the authority to promulgate the Clean Unit provisions, and the Court requested that EPA vacate that portion of the 2002 Federal regulation, codified at 40 CFR 52.21(x), as contrary to the statute. Also, the Court determined that EPA lacked the authority to create PCP exceptions from NSR and vacated those parts of the 1991 and 2002 rules, codified at 40 CFR 52.21(b)(32) and 52.21(z), as contrary to the statute.

As stated in the December 31, 2002 ''NSR Reform'' rulemaking, State and local permitting agencies were required to adopt and submit revisions to their part 51 permitting programs, implementing the minimum program elements of that rulemaking no later than January 2, 2006 (67 FR 80240). With this submittal, Virginia requests approval of program revisions to satisfy this requirement. In addition, Virginia has updated their stationary source permit regulations in Chapter 50, Article 4, to conform to the new NSR regulatory program and translated the Federal NSR requirements into their regulatory text in Chapter 80, Article 9 in a manner that is consistent with State regulatory development procedures.

On February 14, 2007, EPA Region III received a revision request to the Virginia SIP from the Virginia Department of Environmental Quality (VADEQ). The February 14, 2007 SIP revision request consisted of changes to Legislative Rule 9 VAC 5 Chapter 50 Article 4—Stationary Sources, 9 VAC 5 Chapter 80 Article 6—Permits for New and Modified Stationary Sources, and 9 VAC 5 Chapter 80 Article 9—Permits for Construction and Major Modification of Major Stationary Sources of Air Pollution which Cause or Contribute to Nonattainment. These rules were adopted by the Commonwealth of Virginia State Air Pollution Control Board on June 21, 2006 and became effective September 1, 2006. The Commonwealth adopted the regulations in order to meet the relevant plan requirements of 40 CFR 51.165.

II. Summary of SIP Revision

What is being addressed in this document?

Virginia currently has an EPA-approved NSR program for new and modified sources. Today, EPA is proposing limited approval of the Virginia pre-construction permitting program as submitted on February 12, 2007 for facilities located or locating in nonattainment areas. This revision submittal consists of rules titled ''Chapter 50, Article 4—Stationary Sources'', and ''Chapter 80, Article 9—Permits for Construction and Major Modification of Major Stationary Sources of Air Pollution Which Cause or Contribute to Nonattainment'' adopted June 21, 2006 and effective September 1, 2006. Virginia also submitted changes to 9 VAC Chapter 80 Article 6—Permits for New and Modified Stationary Sources as part of the SIP revision, however, Article 6 has not previously been approved as part of the Virginia SIP and EPA will not be taking any rulemaking action on this portion of the SIP submittal at this time.

Additionally, on December 16, 2003, Virginia submitted a revision to Chapter 80, Article 9 that made a number of changes to comply with the 1990 Amendments to the CAA, the primary of which was to redefine the offset ratio requirements to accommodate the requirements of Subpart I of Part C of Title I of the Act. EPA is proposing full approval of the December 16, 2003 revision submittal.

Today's action will revise the previously approved versions of these rules as approved into the Virginia SIP on April 21, 2000 (65 FR 21315) and September 21, 1999 (64 FR 51047), respectively.

Copies of the revised Virginia rules and submittal packages, as well as the Technical Support Document (TSD), can be obtained from the Docket as discussed in the ''Docket'' Section above. A discussion of notable Virginia rule changes that are proposed for inclusion into the SIP are included in the TSD and also summarized below.

What are the program changes that EPA is proposing limited approval?

In its December 2002 regulatory action, EPA dramatically changed many aspects of the regulations governing the PSD and nonattainment NSR programs (together, as ''NSR''), aimed at ''providing much needed flexibility and regulatory certainty, and at removing barriers and creating incentives for sources to improve environmental performance through emissions reductions, pollution prevention, and improved energy efficiency.'' Virginia accepted the conceptual framework of EPA's NSR reform revisions but tailored the program to their State-specific objectives. EPA agrees that Virginia's regulations, while different in some limited respects, will not prevent companies from benefiting from most, if not all of the goals of NSR reform. In general, EPA has concluded that Virginia's regulations, overall, conform to the minimum program elements in 40 CFR 51.165 despite some variations in their rules from the federal program. It is EPA's position that every element of NSR reform is present in Virginia's rules but these elements may be implemented in a way that allows the Commonwealth more scrutiny with respect to how NSR applies to a facility. The Virginia NSR regulations for nonattainment areas, effective September 1, 2006 are being proposed for limited approval today. The following describes areas within these regulations that vary from the Federal program.

Notable Variations in Article 9 From the Federal Program

1. In the EPA regulations, the period used for establishing the baseline for each pollutant can be different for each pollutant. The Virginia regulations require that it be the same for all pollutants, except where extenuating circumstances would allow use of

different baseline periods. This variation is acceptable to EPA.

2. The EPA regulations do not specify consequences where the owner determines there is a reasonable possibility that a project that is not a part of a major modification may result in a significant emissions increase and does not obtain a permit. The Virginia regulations specify how the state will act should the owner fail to make an accurate determination. EPA believes that this variation from the federal rule has no impact on approvability or the Commonwealth's ability to achieve the goals of NSR reform and is acceptable to EPA.

Please note, the Commonwealth will soon be revising this Section of its regulations to reflect changes made in the EPA final rule dated December 14, 2007 providing improvements to EPA's New Source Review program regarding ''reasonable possibility'' in recordkeeping. This final rule provided an explanation and more detailed criteria to clarify the ''reasonable possibility'' recordkeeping and reporting standard of the 2002 New Source Review Reform rule. The improvements provided in the December 14, 2007 rulemaking were to reflect the amendments found necessary to respond to the decision of the U.S. Court of Appeals for the DC Circuit in *New York* v. *EPA,* 413 F.3d 3 (DC Cir. 2005) (New York) which remanded this portion of the December 2002 regulations for EPA to provide an acceptable explanation for its ''reasonable possibility'' standard or to devise an appropriately supported alternative.

3. The EPA regulations exclude emission increases that could be accommodated and are unrelated to the project, including demand growth, from projected actual emissions. The Virginia regulations included this exclusion but have been revised in order to clarify the intent of the provision and ensure consistency in its application. This variation is acceptable to EPA.

4. The EPA regulations require owners to develop and maintain information to support their determination that a given project is not a part of a major modification that may result in a significant emissions increase. The Virginia regulations require advance notification of the availability of the information prior to beginning actual construction of the project. This variation is acceptable to EPA.

5. The EPA regulations establish Plantwide Applicability Limits (PALs) with a duration of 10 years; the Virginia regulations contain five-year durations for PALs. This variation is acceptable to EPA.

6. This SIP revision also includes other non-substantive changes to Virginia's Nonattainment New Source Review program. There was a need to update regulatory citations, making consistency revisions to the text to bring the regulations in the Commonwealth up to date. EPA's analysis has found that these non-substantative changes do not change any of the minimum regulatory requirements and are acceptable.

Once again, the TSD, (located in the Docket), can be reviewed for an in-depth and full explanation of EPA's regulatory analysis of the Virginia Nonattainment New Source Review program.

III. Limited Approval

Why is EPA proposing ''limited approval'' versus ''full approval'' of Virginia's NSR regulations, effective September 1, 2006 for Nonattainment NSR areas?

The Clean Air Act does not expressly provide for limited approvals, therefore EPA is using its gap-filling authority under section 301(a) of the Act in conjunction with the section 110(k)(3) approval provision to interpret the Act to provide for this type of limited approval action. A key aspect of these limited approval actions is that they encompass the entire rule based on the fact that even with limitations, the approval of the entire rule will strengthen the Commonwealth's SIP. The primary advantage to using this limited approval is that it will make the Commonwealth's revision submittal Federally enforceable and will increase the SIP's potential to achieve additional reductions.

The following is an explanation for this limited approval of the SIP revision by EPA. In Virginia's regulations under 9 VAC 5–80–2010 a new definition was added to reflect the necessary changes to the program found in the 2002 Federal NSR Reform rule.

Virginia's definition for ''baseline actual emissions'' varies from the Federal definition at 40 CFR 51.166(b)(47) in two ways. First, for both electric generating units (EGUs) and non-EGUs, Virginia's rule allows the use of different baselines for different pollutants if the owner can demonstrate to the satisfaction of the State Air Pollution Control Board (Board) that a different baseline period for a different pollutant(s) is more appropriate due to extenuating circumstances. This is acceptable to EPA. However in the second instance, for non-EGUs, the 24-month baseline period must occur within the five-year period preceding the date the owner begins actual construction or the permit application is deemed complete, whichever is earlier, unless the Board allows a different time period that it deems is more representative of normal source operations. The allowance of a different or an extended time period by the Board is acceptable as it allows a time period past the more limiting 5-year period, however, the Commonwealth's regulations do not further restrict the Board from allowing a time period which could extend past the 10-year period currently provided in the Federal NSR Reform rule.

The Virginia regulations, therefore, meet the general Federal criteria for expanding the lookback period beyond the old requirement of the most recent 24-month period, and are thus equivalent to the Federal requirement. The purpose of an extended lookback is to establish a period that is most representative of source operation. Establishment of the most representative operation not only enables sources to plan effective emissions control strategies, it also provides Virginia with more accurate information on which to base long-term air quality planning strategies. The 5-year lookback period can be seen to be more limiting or at times more restrictive than the Federal rule. Requiring a 5-year lookback instead of a 10-year lookback may, however, limit a source's potential to find a higher baseline. This could in turn restrict a source's ability to emit and is thus inherently more protective than the EPA regulations. As part of the February 12, 2007 SIP revision submittal, the Commonwealth provided a more detailed explanation of the 5-year lookback period.

Though it was not Virginia's intention to exceed the 10-year lookback limitation, EPA's decision to propose limited approval is based the Commonwealth's interpretation of its own regulations as provided in their Technical Support Document. EPA is relying on this interpretation of the regulations as noted above and in part, the basis for our limited approval. Furthermore, EPA would look unfavorably upon any use of discretion by Virginia that would allow for baselines that exceed a 10-year lookback period. EPA expects Virginia to correct the definition at 9 VAC 5–80–2010 by limiting the discretionary lookback period to 10 years. When Virginia makes this amendment, they will be eligible for consideration for full approval of its Nonattainment NSR program found in Article 9.

IV. Full Approval

What is EPA proposing full approval of in this action?

On December 16, 2003, the Commonwealth of Virginia submitted a SIP revision submittal for Chapter 80, Article 9 that made a number of changes to comply with the 1990 Amendments to the CAA, the primary of which was to redefine the offset ratio requirements to accommodate the requirements of subpart I of part C of title I of the Act. Additionally, administrative permit processing provisions were also clarified further within this submission. EPA is proposing full approval of the December 16, 2003 revision submittal.

V. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

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

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

Virginia's Immunity law, Va. Code Section 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.''

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

VI. Proposed Action

EPA has determined that the amendments to Virginia's nonattainment new source review permit program at Articles 4 and 9, as submitted on February 12, 2007 meet the minimum requirements of 40 CFR 51.165 and the Clean Air Act. This amendment is being proposed as a limited approval as described in Section III above, as a revision to the Virginia SIP. EPA is also proposing full approval of changes submitted to the nonattainment new source review permit program at Article 9, as submitted on December 16, 2003 and as described in Section IV above as a revision to the Virginia SIP. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

VII. Statutory and Executive Order Reviews

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

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

health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule for limited approval of the SIP revision submitted on February 12, 2007 and the full approval of the SIP revision submitted on December 16, 2003 for facilities located or locating in nonattainment areas for Virginia nonattainment new source review does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: June 17, 2008.

William T. Wisniewski,

Acting Regional Administrator, Region III.

[FR Doc. E8–14625 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2007–0521; FRL–8686–2]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Virginia Major New Source Review, Prevention of Significant Deterioration (PSD)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing limited approval of a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia. This revision pertains to amendments to Virginia's existing new source review permit program for owners of sources located or locating in prevention of significant deterioration (PSD) areas which were submitted to EPA on October 10, 2006. EPA is proposing limited approval of these changes to the PSD program, because while the SIP revision submitted by the Commonwealth strengthens the SIP, it does not fully meet the current Federal requirements for the allowable lookback period under the definition of ''baseline actual emissions''. This action is being taken under the Clean Air Act (CAA or the Act). In a separate action, EPA will address changes made by Virginia to its nonattainment new source review (NNSR) permit program, submitted on February 12, 2007.

DATES: Written comments must be received on or before July 28, 2008.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2007–0521 by one of the following methods:

A. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *E-mail: campbell.dave@epa.gov*.

C. *Mail:* EPA–R03–OAR–2007–0521, David Campbell, Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2007–0521. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Sharon McCauley, (215) 814–3376, or by e-mail at *mccauley.sharon@epa.gov*.

SUPPLEMENTARY INFORMATION: On October 10, 2006, the Commonwealth of Virginia submitted a revision to its SIP for approval of amendments to Virginia's existing New Source Review permit program for owners of sources locating in PSD areas.

I. Background

On December 31, 2002, the U.S. EPA published revisions to the Federal PSD and NNSR regulations (67 FR 80186), effective March 3, 2003. These changes to the Federal NSR regulations were reconsidered with minor changes on November 7, 2003 (68 FR 63021) and collectively, these two final actions are called the ''2002 New Source Review (NSR) Reform Rules''.

The 2002 NSR Reform Rules made changes to five areas of the NSR programs. In summary, the 2002 Rules: (1) Provide a new method for determining the baseline actual emissions; (2) adopt an actual-to-projected actual methodology for determining whether a major modification has occurred; (3) allow major stationary sources to comply with plant-wide applicability limits to avoid having a significant emissions increase that triggers the requirements of the major NSR program; (4) provide a new applicability provision for emissions units that are designated clean units; and (5) exclude pollution control projects (PCPs) from the definition of ''physical change or change in the method of operation.'' The November 7,

2003 notice of final action added a definition for ''replacement unit'' and clarified an issue regarding the Plant-wide Applicability Limitation (PALs) baseline calculation procedures for newly constructed units.

On June 24, 2005, the United States Court of Appeals for the District of Columbia Circuit ruled in *New York* v. *EPA,* 413 F.3d 3 (DC Cir. June 24, 2005) that EPA lacked the authority to promulgate the Clean Unit provisions, and the Court requested that EPA vacate that portion of the 2002 Federal regulation, codified at 40 CFR 52.21(x), as contrary to the statute. Also, the Court determined that EPA lacked the authority to create PCP exceptions from NSR and vacated those parts of the 1991 and 2002 rules, codified at 40 CFR 52.21(b)(32) and 52.21(z), as contrary to the statute.

As stated in the December 31, 2002 ''NSR Reform'' rulemaking, State and local permitting agencies were required to adopt and submit revisions to their part 51 permitting programs, implementing the minimum program elements of that rulemaking no later then January 2, 2006 (67 FR 80240). With this submittal, Virginia requests approval of program revisions to satisfy this requirement. In addition, Virginia has updated their stationary source permit regulations in Chapter 50, Article 4, to conform to the new NSR regulatory program and translated the Federal NSR requirements into their regulatory text in Chapter 80, Article 8 in a manner that is consistent with State regulatory development procedures.

On October 13, 2006, EPA Region III received a revision request to the Virginia SIP from the Virginia Department of Environmental Quality (VADEQ). The October 13, 2006, 2006 SIP revision request consisted of changes to Legislative Rule 9 VAC 5 Chapter 50 Article 4—Stationary Sources, 9 VAC 5 Chapter 80 Article 6—Permits for New and Modified Stationary Sources, and 9 VAC 5 Chapter 80 Article 8—Permits for Construction and Major Modification of Major Stationary Sources of Air Pollution for the Prevention of Significant Deterioration. These rules were adopted by the Commonwealth of Virginia State Air Pollution Control Board on June 21, 2006 and became effective September 1, 2006. The Commonwealth adopted the regulations in order to meet the relevant plan requirements of 40 CFR 51.166.

II. Summary of SIP Revision

What is being addressed in this document?

Virginia currently has an EPA-approved NSR program for new and modified sources. Today, EPA is proposing limited approval of the Virginia pre-construction permitting program as submitted on October 10, 2006 for sources located or locating in PSD areas. The submittal consists of rules titled ''Chapter 50, Article 4—Stationary Sources'' and ''Chapter 80, Article 8—Permits for Construction and Major Modification of Major Stationary Sources of Air Pollution for the Prevention of Significant Deterioration (PSD)'' adopted June 21, 2006 and effective September 1, 2006. Virginia also submitted changes to 9 VAC Chapter 80 Article 6—Permits for New and Modified Stationary Sources as part of the SIP revision, however, Article 6 has not previously been approved as part of the Virginia SIP and EPA will not be taking any rulemaking action on this portion of the SIP submittal at this time. This limited approval action will revise the previously-approved versions of these rules as approved into the Virginia SIP on April 21, 2000 (65 FR 21315) and March 23, 1998 (63 FR 13795).

Copies of the revised Virginia rules, as well as the Technical Support Document (TSD), can be obtained from the Docket as discussed in the ''Docket'' Section above. A discussion of the notable Virginia rule changes that are proposed for inclusion into the SIP are included in the TSD and summarized below.

What are the program changes that EPA is proposing limited approval?

In its December 2002 regulatory action, EPA dramatically changed many aspects of the regulations governing the PSD and nonattainment NSR programs (together, as ''NSR''), aimed at providing much needed flexibility and regulatory certainty, and at removing barriers and creating incentives for sources to improve environmental performance through emissions reductions, pollution prevention, and improved energy efficiency.'' Virginia accepted the conceptual framework of EPA's NSR reform revisions but tailored the program to their State-specific objectives. EPA agrees that Virginia's regulations, while different in some limited respects, will not prevent companies from benefiting from most, if not all of the goals of NSR reform. In general, EPA has concluded that Virginia's regulations, overall, conform to the minimum program elements in 40 CFR 51.166 despite some variations in their rules from the federal program. These notable variations are described below and the explanation of EPA's proposed limited approval is described in Section III of this notice.

Notable Variations in Article 8 From the Federal Program

1. In the EPA regulations, the period used for establishing the baseline for each pollutant can be different for each pollutant. The Virginia regulations require that it be the same for all pollutants, except where extenuating circumstances would allow use of different baseline periods. This variation is acceptable to EPA.

2. The EPA regulations do not specify consequences where the owner determines there is a reasonable possibility that a project that is not a part of a major modification may result in a significant emissions increase and does not obtain a permit. The Virginia regulations specify how the state will act should the owner fail to make an accurate determination. EPA believes that this variation from the Federal rule has no impact on approvability or the Commonwealth's ability to achieve the goals of NSR reform and is acceptable to EPA.

Please note, the Commonwealth will soon be revising this Section of its regulations to reflect changes made in the EPA final rule dated December 14, 2007 providing improvements to EPA's New Source Review program regarding ''reasonable possibility'' in recordkeeping. EPA's final rule provided an explanation and more detailed criteria to clarify the ''reasonable possibility'' recordkeeping and reporting standard of the 2002 New Source Review Reform rule. The improvements provided in the December 14, 2007 rulemaking were to reflect the amendments found necessary to respond to the decision of the U.S. Court of Appeals for the DC Circuit in *New York* v. *EPA*, 413 F.3d 3 (DC Cir. 2005) (New York) which remanded this portion of the December 2002 regulations for EPA to provide an acceptable explanation for its ''reasonable possibility'' standard or to devise an appropriately supported alternative.

3. The EPA regulations exclude emission increases that could be accommodated and are unrelated to the project, including demand growth, from projected actual emissions. The Virginia regulations included this exclusion but have been revised in order to clarify the intent of the provision and ensure consistency in its application. This variation is acceptable to EPA.

4. The EPA regulations require owners to develop and maintain information to support their determination that a given project is not a part of a major modification that may result in a significant emissions increase. The Virginia regulations require advance notification of the availability of the information prior to beginning actual construction of the project. This variation is acceptable to EPA.

5. The EPA regulations establish Plantwide Applicability Limits (PALs) with a duration of 10 years; the Virginia regulations contain five-year durations for PALs. This variation is acceptable to EPA.

6. This SIP revision also includes other non-substantive changes to Virginia's PSD program. There was a need to update regulatory citations, making consistency revisions to the text to bring the regulations in the Commonwealth up to date. EPA's analysis has found that these non-substantative changes do not change any of the minimum regulatory requirements and are acceptable.

For an in-depth and full explanation of EPA's regulatory analysis of the Virginia PSD program, please review the TSD located in the Docket. EPA's position is that every element of NSR reform is present in Virginia's rules but some elements may be implemented in a way that allows the Commonwealth more scrutiny with respect to how NSR applies to a facility.

III. Limited Approval

Why is EPA proposing ''limited approval'' versus ''full approval'' of Virginia's NSR Reform regulations for PSD areas?

The Clean Air Act does not expressly provide for limited approvals, therefore EPA is using its gap-filling authority under section 301 (a) of the Act in conjunction with the section 110(k)(3) approval provision to interpret the Act to provide for this type of limited approval action. A key aspect of these limited approval actions is that they encompass the entire rule based on the fact that even with limitations, the approval of the entire rule will strengthen the Commonwealth's SIP. The primary advantage to using this limited approval is that it will make the Commonwealth's revision submittal Federally enforceable and will increase the SIP's potential to achieve additional reductions.

The following is an explanation for the limited approval of this SIP revision by EPA. In Virginia's regulations under 9 VAC 5–80–1615 a new definition was added to reflect the necessary changes to the program found in the 2002 Federal NSR Reform rule.

Virginia's definition for ''baseline actual emissions'' varies from the Federal definition at 40 CFR 51.166(b)(47) in two ways. First, for both electric generating units (EGUs) and non-EGUs, Virginia's rule allows the use of different baselines for different pollutants if the owner can demonstrate to the satisfaction of the State Air Pollution Control Board (Board) that a different baseline period for a different pollutant(s) is more appropriate due to extenuating circumstances. This is acceptable to EPA. However in the second instance, for non-EGUs, the 24-month baseline period must occur within the five-year period preceding the date the owner begins actual construction or the permit application is deemed complete, whichever is earlier, unless the Board allows a different time period that it deems is more representative of normal source operations. The allowance of a different or an extended time period by the Board is acceptable as it allows a time period past the more limiting 5-year period; however, the Commonwealth's regulations do not further restrict the Board from allowing a time period which could extend past the 10-year period currently provided in the federal NSR Reform rule.

The Virginia regulations, therefore, meet the general federal criteria for expanding the lookback period beyond the old requirement of the most recent 24-month period, and are thus equivalent to the federal requirement. The purpose of an extended lookback is to establish a period that is most representative of source operation. Establishment of the most representative operation not only enables sources to plan effective emissions control strategies, it also provides Virginia with more accurate information on which to base long-term air quality planning strategies. The 5-year lookback period can be seen to be more limiting or at times more restrictive than the Federal rule. Requiring a 5-year lookback instead of a 10-year lookback may, however, limit a source's potential to find a higher baseline. This could in turn restrict a source's ability to emit and is thus inherently more protective than the EPA regulations. As part of the October 10, 2006 SIP revision submittal, the Commonwealth provided a more detailed explanation of the 5-year lookback period.

Though it was not Virginia's intention to exceed the 10-year lookback period limitation, EPA's decision to propose limited approval is based on the Commonwealth's interpretation of its own regulations as provided in their Technical Support Document. EPA is relying on this interpretation of the regulations as noted above and in part, the basis for our limited approval. Furthermore, EPA would look unfavorably upon any use of discretion by Virginia that would allow for baselines that exceed a 10-year lookback period. EPA expects Virginia to correct the definition at 9 VAC 5–80–1615 by limiting the discretionary lookback period to 10 years. When Virginia makes this amendment, they will be eligible for consideration for full approval of its PSD program found in Article 8.

IV. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

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

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law'', including documents and information ''required by Federal law to maintain program delegation, authorization or

approval, since Virginia must ''enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts ''* * *.'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.

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

V. Proposed Action

EPA has determined that the amendments to Virginia's PSD permit program at Articles 4 and 8, as submitted on October 10, 2006 meet the minimum requirements of 40 CFR 51.166 and the Clean Air Act. This amendment is being proposed as a limited approval to the Virginia SIP. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

VI. Statutory and Executive Order Reviews

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

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

In addition, this proposed rule for limited approval of the Virginia Major New Source review Reform for facilities located or locating in PSD areas does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: June 17, 2008.

William T. Wisniewski,

Acting Regional Administrator, Region III.

[FR Doc. E8–14617 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2007–0998; FRL–8684–2]

Approval and Promulgation of State Implementation Plans: Washington; Vancouver Air Quality Maintenance Area; Second 10-Year Carbon Monoxide Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Washington. The Washington State Department of Ecology submitted the Vancouver Air Quality Maintenance Area Second 10-year Carbon Monoxide Maintenance Plan on April 25, 2007. In accordance with the requirements of the Federal Clean Air Act (the Act), EPA is proposing to approve Washington's revision because the State adequately demonstrates that the Vancouver Air Quality Maintenance Area will maintain air quality standards for carbon monoxide (CO) through the year 2016.

DATES: Comments must be received on or before July 28, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2007–0998, by any of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: vaupel.claudia@epa.gov.*
- *Mail:* Claudia Vergnani Vaupel, U.S. EPA Region 10, Office of Air, Waste and Toxics (AWT–107), 1200 Sixth Avenue, Suite 900, Seattle, WA 98101.

• *Hand Delivery/Courier:* U.S. EPA Region 10, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. Attention: Claudia Vergnani Vaupel, Office of Air, Waste and Toxics, AWT–107. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Claudia Vergnani Vaupel at telephone number: (206) 553–6121, e-mail address: *vaupel.claudia@epa.gov*, fax number: (206) 553–0110, or Gina Bonifacino at telephone number: (206) 553–2970, e-mail address: *bonifacino.gina@epa.gov*, or the above EPA, Region 10 address.

SUPPLEMENTARY INFORMATION: For further information, please see the direct final action, of the same title, which is located in the Rules section of this **Federal Register**. EPA is approving the State's SIP revision as a direct final rule without prior proposal because EPA views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the preamble to the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule.

If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: June 10, 2008.

Michelle Pirzadeh,

Acting Regional Administrator, EPA Region 10.

[FR Doc. E8–14519 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2006–0040; FRL–8685–9]

Approval, Disapproval, and Promulgation of Air Quality Implementation Plans; Montana; Kraft Pulp Mill Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to partially approve and partially disapprove the Kraft Pulp Mill Rule and Visible Air Contaminants Rule that the Governor of Montana submitted to us on April 14, 1999. EPA is also proposing to partially approve the recodification of the Kraft Pulp Mill Rule that the Governor submitted to us on September 19, 1997. These revisions recodify and make changes to the State's Kraft Pulp Mill Rule, including the establishment of certain new opacity requirements for kraft pulp mills, and modify the Visible Air Contaminant Rule requirements for recovery furnaces at kraft pulp mills. The intended effect of this action is to approve and make federally enforceable those portions of the rules that meet Clean Air Act requirements, and to disapprove those portions of the rules that are inconsistent with the Clean Air Act. The EPA is taking this action under section 110 of the Clean Air Act (Act).

DATES: Comments must be received on or before July 28, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2006–0040, by one of the following methods:

• *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *E-mail: videtich.callie@epa.gov* and *russ.tim@epa.gov*.

• *Fax:* (303) 312–6064 (please alert the individual listed in **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).

• *Mail:* Callie A. Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.

• *Hand Delivery:* Callie A. Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2006–0040. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*. For additional instructions on submitting comments, go to section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION**

CONTACT section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tim Russ, Air Program, Mailcode 8P-AR, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6479, or russ.tim@epa.gov.

SUPPLEMENTARY INFORMATION:

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II. Background of the State Submittals
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IV. Proposed Action
V. Statutory and Executive Order Reviews

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The word *Act* or initials *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *NAAQS* means National Ambient Air Quality Standard.

(iv) The initials *SIP* mean or refer to State Implementation Plan.

(v) The words *State* or *Montana* mean the State of Montana, unless the context indicates otherwise.

I. General Information

a. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through http://www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

A. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

B. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

C. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

D. Describe any assumptions and provide any technical information and/or data that you used.

E. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

F. Provide specific examples to illustrate your concerns, and suggest alternatives.

G. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

H. Make sure to submit your comments by the comment period deadline identified.

II. Background of the State Submittals

On April 14, 1999 the Governor of Montana submitted a SIP revision that contained changes to the State's Kraft Pulp Mill Rule, Visible Air Contaminant Rule, and Incorporation by Reference Rule that had been adopted by the Montana Board of Environmental Review (MBER) on May 19, 1995 and December 11, 1998 [1]. Montana's Kraft Pulp Mill Rule, currently codified at ARM 17.8.321, applies to only one source, Smurfit-Stone Container in Missoula, Montana. The SIP revision changes opacity limits at Smurfit-Stone Container's recovery furnaces #3, #4, and #5, as described more fully below.

a. MBER's May 19, 1995 Revisions

The revisions MBER adopted on May 19, 1995 added definitions for ''cross recovery furnace,'' ''recovery furnace,'' and ''straight kraft recovery furnace,'' (ARM 16.8.1413(1)(b), (f) and (h)); made minor revisions to ARM 16.8.1413(7); and added ARM 16.8.1413(8) through (12).[2] ARM 16.8.1413(8) through (12) contained opacity limits on recovery furnaces as well as the compliance monitoring methods for the opacity limitations and reporting requirements. The revised rule resulted in a 35% opacity limit on recovery furnace #3 and a 30% opacity limit on recovery furnaces #4 and #5. The revised rule also required Smurfit-Stone to install continuous opacity monitors (COMS) on the three recovery furnace stacks. Additionally, on May 19, 1995, the MBER adopted a new provision (ARM 16.8.1404(4)(f) later recodified as ARM 17.8.304(4)(f) and submitted to us on September 19, 1997 [3]), which provided that Montana's general opacity requirements in ARM 16.8.1404 did not apply to recovery furnaces at kraft pulp mills. These general opacity requirements require sources installed on or before November 23, 1968 to meet a 40% opacity limitation and sources installed after November 23, 1968 to meet a 20% opacity limitation.

b. MBER's December 11, 1998 Revisions

On December 11, 1998, MBER adopted further changes and additions to the Kraft Pulp Mill Rule, including changes to the May 1995 opacity limits applicable to recovery furnaces #4 and #5. These changes and additions were codified at ARM 17.8.321(9) through (16). ARM 17.8.321(9) (applicable to recovery furnace #4) requires that, for recovery furnaces installed after November 23, 1968, no person may cause or authorize emissions that exhibit 20% opacity or greater averaged over 6 consecutive minutes for more than 6% of the 6-minute time periods during which a source is operating in a calendar quarter. ARM 17.8.321(10) (applicable to recovery furnace #5) requires that, for recovery furnaces installed after September 4, 1976, no person may cause or authorize emissions that exhibit 20% opacity or greater averaged over 6 consecutive minutes for more than 3% of the 6-minute time periods during which a source is operating in a calendar quarter. ARM 17.8.321(11) defines excess opacity emissions. ARM 17.8.321(12) indicates that sources subject to ARM 17.8.321(9) and (10) may not emit opacity greater than 20% averaged over 24 hours. ARM 17.8.321(13) requires recovery furnaces and associated air pollution control equipment to be operated in accordance with good air pollution control practices during excess opacity emissions. Finally, ARM 17.8.321(14), (15), and (16) contain revisions to the compliance monitoring methods and reporting requirements for kraft pulp mills.

[1] On August 13, 2001 (66 FR 42427), we approved the changes to the Incorporation by Reference Rule (ARM 17.8.302) that MBER adopted on May 19, 1995; no further discussion of the Incorporation by Reference Rule is included in this action.

[2] These rules were later recodified; ARM 16.8.1413(1) through (12) were changed to ARM 17.8.321(1) through (12). This recodification was submitted to us on September 19, 1997 as part of a general recodification of Montana's air rules.

[3] In a separate rulemaking action published on August 13, 2001 (66 FR 42427), we approved most of the recodification of the Administrative Rules of Montana submitted on September 19, 1997. We did not approve the codification of ARM 17.8.321, Kraft Pulp Mill Rule, or ARM 17.8.304(4)(f) of the Visible Air Contaminants Rule. In our August 13, 2001 action, we indicated that we would address the revisions to ARM 17.8.304(4)(f) and 17.8.321 at a later date.

III. EPA Analysis of the State Submittals

a. ARM 17.8.321(1) Through (7), Adopted May 19, 1995, Effective August 11, 1995, and Submitted April 14, 1999

The State merely added definitions, made editorial changes, and recodified the rule. Because the changes are consistent with Clean Air Act requirements, we are proposing to approve into the SIP ARM 17.8.321(1) through (7) (formerly codified as ARM 16.8.1413(1) through (7)). We are also proposing that ARM 17.8.321(1) through (7) will replace the old codified version of the Kraft Pulp Mill Rule (ARM 16.8.1413(1) through (7), effective December 31, 1972) that is currently in the SIP.

b. ARM 17.8.321(8), Adopted May 19, 1995, Effective August 11, 1995, Submitted April 14, 1999; and ARM 17.8.321(9) and (10), Adopted December 11, 1998, Effective February 12, 1999, and Submitted April 14, 1999

The table below shows the opacity limits in ARM 17.8.321(8), (9) and (10) as compared to the existing SIP opacity limits for Smurfit-Stone's three recovery furnaces.

Smurfit-Stone recovery furnace impacted	Installation date	Opacity limit six-minute average (existing SIP-Approved rule, ARM 17.8.304)	Opacity limit *** six-minute average (revised rule, ARM 17.8.321)	Exceedance allowance with revised rule
Furnace #3	On or before 11/23/68.	40% * ARM 17.8.304(1)	35% ARM 17.8.321(8)	None.
Furnace #4	After 11/23/68	20% * ARM 17.8.304(2)	20% ARM 17.8.321(9) ****	6% of the 6-minute periods during which a source is operating within any calendar quarter.
Furnace #5	After 9/4/76	35% ** ARM 17.8.304(4)	20% ARM 17.8.321(10) ****	3% of the 6-minute periods during which a source is operating within any calendar quarter.

* Sources not allowed to exceed opacity limit except a maximum opacity of 60% is permissible for not more than one 4-minute period in any 60 consecutive minutes during the building of new fires, cleaning of grates, or soot blowing (ARM 17.8.304(3)).

** ARM 17.8.304(4)(d) indicates that the 20% opacity standard in ARM 17.8.304(2) does not apply to "those new stationary sources listed in ARM 17.8.340 for which a visible emission standard has been promulgated." ARM 17.8.340 cross-references EPA's New Source Performance Standards (NSPS). Under the State's interpretation, Furnace #5 is thus subject to the NSPS opacity standard for kraft pulp mills instead of the 20% SIP standard. The NSPS opacity standard is 35% with a 6% quarterly exceedance allowance. See 40 CFR 60.284(d) and (e).

*** Sources not allowed to exceed opacity limit except for any exceedance allowance.

**** ARM17.8.321(12) contains an additional requirement that applies to recovery furnaces #4 and #5: Opacity of 20% or greater as averaged over 24 hours is not permitted.

Among other things, EPA evaluates SIP revisions against section 110(l) of the Act. Section 110(l) of the Act provides that we cannot approve a revision to a SIP if the revision would interfere with any applicable requirements concerning attainment and reasonable further progress (RFP), or any other applicable requirement of the Act.

Our evaluation of the changes to ARM 17.8.321(8), (9), and (10) with respect to section 110(l) of the Act is as follows:

1. *ARM 17.8.321(8):* We are proposing to approve ARM 17.8.321(8) because it does not contain an opacity exceedance allowance and it imposes a more stringent opacity limit than the existing SIP on recovery furnaces installed on or before November 23, 1968. Thus, no increase in particulate matter emissions is expected from this change. Accordingly, this revision would not interfere with any applicable requirements concerning attainment and reasonable further progress (RFP), or any other applicable requirement of the Act.

However, we are concerned that the second sentence of ARM 17.8.321(8), which applies to Smurfit-Stone recovery furnace #3, could be read more broadly than is appropriate. That sentence indicates that the opacity limit in ARM 17.8.321(8) "supersedes any other opacity limitation contained in this chapter, including ARM 17.8.304 and 17.8.340." ARM 17.8.340 requires compliance with the New Source Performance Standards (NSPS) in 40 CFR part 60. In our view, a SIP rule cannot "supersede" a federal standard such as the NSPS; instead, the NSPS is another requirement that may apply to a source. A source is obligated to comply with the SIP's opacity provisions for recovery furnaces and the NSPS.

Accordingly, we note that while ARM 17.8.321(8) states that its opacity limit supersedes "any other opacity limitation contained in this chapter" (emphasis added), it does not say that its opacity limit supersedes the federally-established opacity limits contained in 40 CFR Part 60. Thus, it is our interpretation that ARM 17.8.321(8) does not supersede the requirements of 40 CFR Part 60; instead, we interpret ARM 17.8.321(8) as establishing an additional standard. To the extent ARM 17.8.321(8) and 40 CFR Part 60 are both applicable, the source must comply with both. In this case, because ARM 17.8.321(8) is more stringent than the current NSPS opacity standards applicable to kraft pulp mill recovery furnaces, compliance with ARM 17.8.321(8) should ensure compliance with the NSPS opacity standard.

2. *ARM 17.8.321(9):* We are proposing to disapprove ARM 17.8.321(9). Although the opacity limit of 20% in ARM 17.8.321(9) is the same numeric opacity limit that is contained in the approved SIP, ARM 17.8.321(9) contains an exceedance allowance that is not in the approved SIP. The exceedance allowance allows the source to exceed its opacity limit a certain percentage of time each quarter; in ARM 17.8.321(9), the exceedence allowance is 6% of the 6-minute time periods during which the source is operating. While the source is also subject to an average daily opacity limit of 20%, per ARM 17.8.321(12), our analysis indicates that even with this restriction, the opacity limit in ARM 17.8.321(9) would be less stringent than the existing SIP opacity limit (which is based on a six-minute average, not daily) and could lead to an increase in particulate matter emissions, as calculated using the source-supplied correlation between opacity and particulate matter. Our analysis considers potential effects on attainment of the PM_{10} and $PM_{2.5}$ NAAQS and compliance with the PM_{10} increment under the Clean Air Act's Prevention of Significant Deterioration (PSD) provisions.

Regarding the PM_{10} NAAQS, we note that the PM_{10} limit on Smurfit-Stone recovery furnace #4 was relied on to help demonstrate attainment of the PM_{10} NAAQS in Missoula County, Montana. Therefore, to show compliance with the requirements of section 110(l) of the CAA, it would be necessary to demonstrate that the revision to the opacity limit would not interfere with continued attainment of the PM_{10} NAAQS and that the PM_{10} limits on recovery furnace #4 would be met during the exceedance allowance, assuming the 20% restriction on the average daily opacity contained in ARM 17.8.321(12).[4]

Relative to this issue, the Montana Department of Environmental Quality (MDEQ) provided testimony to the MBER for its proposed revisions to the Kraft Pulp Mill Rule. In its testimony, the MDEQ attempted to show the effect of an opacity exceedance allowance on the PM_{10} mass emissions for Smurfit-Stone's recovery furnace #4. The MDEQ concluded that the mass emissions allowed by the State's proposed changes to the Kraft Pulp Mill Rule would be comparable to those allowed by the current SIP. In order to make this comparison, the MDEQ assumed the average opacity during use of the exceedance allowance would not exceed the 20% standard by more than 10%; thus, 30% was the estimated average opacity during exceedance periods. Additionally, MDEQ estimated particulate emissions using a correlation equation developed by Smurfit-Stone[5] and assuming average air flow to the recovery furnaces.

We believe this approach is flawed for two reasons. First, during Smurfit-Stone's use of the exceedance allowance, the Kraft Pulp Mill Rule does not limit exceedances to 30% opacity; thus, capping the exceedances at 30% is expected to underestimate the predicted particulate emissions. Second, using average, rather than maximum, air flow to the recovery furnaces may also underestimate predicted particulate emissions. Any demonstration to show that the PM_{10} emission limits, and hence the PM_{10} NAAQS, would be met should use worst-case scenarios.

Using worst case scenarios, EPA conducted its own analysis of potential PM_{10} emissions from recovery furnace #4. Like MDEQ, we used Smurfit-Stone's correlation equation for recovery furnace #4. However, we used worst-case assumptions for air flow and opacity levels. Smurfit-Stone's furnace-specific correlation equation is used by Smurfit-Stone and the State to calculate particulate emissions from the furnace and is based on the opacity of furnace emissions and air flow to the furnace. According to the State, the equation is as follows:

Recovery Furnace #4: Particulate emissions (pounds/day) = Q*C*K1*K2

Where:

Q = stack exit air flow in dry standard cubic feet per minute (DSCFM) = 0.2322*(total air) + 14637 (total air = air flow into the boiler (pounds/hour));

C = particulate concentration in grains/dry standard cubic foot (DSCF) = (−0.1303*ln(1−opacity)) + 0.0008; opacity represented as a decimal (10% opacity would be 0.10 in this equation);

K1 = conversion factor (1 pound/7000 grains); and

K2 = conversion factor (1440 minutes/day).

In our analysis, we relied on the following considerations: With a 6% per quarter exceedance allowance, recovery furnace #4 could exceed the 20% opacity limit up to approximately 131 hours per quarter (8760 hours per year/4 quarters per year * 6 % = 131 hours per quarter.) Thus, for a single 24 hour period, recovery furnace #4 could exceed the 20% opacity limit every six-minute period during the 24 hour period and still have the ability to comply with its exceedance allowance for the quarter. This means that, on a 24-hour basis, ARM 17.8.321(12)'s 20% daily average opacity limit for recovery furnace #4 is more controlling than the exceedance allowance.

Accordingly, in our analysis we attempted to determine whether compliance with the 20% daily average opacity limit would ensure compliance with the daily particulate emission limits at recovery furnace #4. Using the correlation equation, potential opacity readings, and maximum gas flow rate, we found that meeting the 20% daily average opacity limit would not assure that the 24-hour PM_{10} emission limits on recovery furnace #4 would be met. Our analysis is contained in the docket to this action.

In addition, the State did not provide us with any basis for concluding that increases in $PM_{2.5}$ emissions would not interfere with attainment of the $PM_{2.5}$ NAAQS, and that increases in PM_{10} emissions would not jeopardize the PM_{10} increment.[6] Based on the State's submittal and our own evaluation, we are unable to conclude that the revision in ARM 17.8.321(9) would not interfere with attainment of the PM_{10} and $PM_{2.5}$ NAAQS or jeopardize the PM_{10} increment. Thus, we are proposing to disapprove ARM 17.8.321(9).

3. *ARM 17.8.321(10):* Because the 20% opacity limit in ARM 17.8.321(10) is more stringent than the 35% opacity limit in the approved SIP, and ARM 17.8.321(10)'s exceedance allowance (3% per quarter) is more stringent than the existing SIP rule's exceedance allowance (6% per quarter), we are proposing to approve ARM 17.8.321(10). No increase in particulate matter emissions is expected from this change. Thus, this revision would not interfere with any applicable requirements concerning attainment and reasonable further progress (RFP), or any other applicable requirement of the Act.

c. ARM 17.8.321(11) Through (16)

ARM 17.8.321(11) indicates that excess opacity emissions for recovery furnaces installed on or before November 23, 1968 means any 6-minute average of 35% or greater and for recovery furnaces installed after November 23, 1968 means any 6-minute average of 20% or greater. ARM 17.8.321(12) indicates that for recovery furnaces subject to ARM 17.8.321(9) and (10), no person may cause or allow emissions that exhibit a 20% opacity or greater as averaged over a 24-hour period. ARM 17.8.321(13) requires recovery furnaces and associated air pollution control equipment to be operated in accordance with good air pollution control practices during any period of excess opacity emissions. Finally, ARM 17.8.321(14), (15), and (16) require recovery furnaces subject to ARM 17.8.321(8), (9), and (10) to install and operate COMS pursuant to certain requirements, and to report excess opacity emissions.

[4] Opacity has long been used as an indicator of compliance with emission limits; if opacity increases, PM emissions are also likely to increase. 40 CFR 51.212 requires that SIPs include opacity limits as a means to detect violations of rules and regulations. Similarly, the NSPS imposes opacity limits but provides the option for sources to petition EPA for a higher opacity limit if the source can show that it complied with all other applicable limits during performance tests under 40 CFR 60.8 but failed to meet its opacity limit. *See* 40 CFR 60.11(e)(6). Our concern is that a relaxation in the kraft pulp mill opacity limit could result in undetected exceedances of the particulate emission limits if compliance with the opacity limit would not necessarily reflect compliance with the PM limits.

[5] Smurfit-Stone has conducted studies to correlate particulate emissions with opacity readings at recovery furnaces #4 and #5, and the resulting correlation equations are used to determine compliance with particulate limits at recovery furnaces #4 and #5.

[6] In a September 25, 1998 letter to the State, we indicated that an evaluation of the impact on the PM_{10} increment must occur because a relaxation of the opacity limit could result in increases in actual emissions from the source. 40 CFR 51.166(a)(2), states ''If a SIP revision would result in increased air quality deterioration over any baseline concentration, the plan revision shall include a demonstration that it will not cause or contribute to a violation.

We note that ARM 17.8.321(15) indicates that COMS will be the primary measure of compliance with the opacity limits in the rule, but that EPA Method 9 may be used as a measure of compliance when there is a reason to believe the COMS data are not accurate or when COMS data are unavailable. We do not believe this language was intended to preclude the use of Method 9 readings as credible evidence of compliance in circumstances other than those specified in the rule, and we propose to interpret the rule accordingly.

Because the above provisions will not reduce the stringency of the existing federally-approved SIP, we consider them to be consistent with the requirements of section 110(l) of the Act. Therefore, we are proposing to approve ARM 17.8.321(11) through (16).

d. ARM 17.8.304(4)(f)

As part of the April 14, 1999 submittal to us, the Governor submitted revisions to ARM 17.8.304, the Visible Air Contaminants Rule. On May 19, 1995, MBER added subsection (f) to ARM 16.8.1404(4) (now codified as ARM 17.8.304(4)(f)). ARM 17.8.304(4)(f) excludes recovery furnaces at kraft pulp mills from the statewide general opacity requirements. We are proposing to disapprove the addition of this paragraph because we are proposing to disapprove ARM 17.8.321(9). If we were to approve the addition of paragraph (4)(f), and disapprove the State's new opacity requirements in ARM 17.8.321(9), kraft pulp mill recovery furnaces installed between November 23, 1968 and September 4, 1976 would not be subject to any EPA-approved SIP opacity limits.

IV. Proposed Action

We are proposing action on the revisions to ARM 17.8.304, ''Visible Air Contaminants,'' and ARM 17.8.321, ''Kraft Pulp Mill Rule,'' that the Governor of Montana submitted to us on April 14, 1999, and on the recodification of the Kraft Pulp Mill Rule that the Governor submitted to us on September 19, 1997.

We are proposing to approve the recodification of, and revisions to, the Kraft Pulp Mill Rule found in ARM 17.8.321(1) through (7) (formerly codified ARM 16.8.1413(1) through (7)). We are also proposing that ARM 17.8.321(1) through (7), if approved, will replace the old codified version of the Kraft Pulp Mill Rule (ARM 16.8.1413(1) through (7), effective December 31, 1972) that is currently in the SIP. We are also proposing to approve the provisions in ARM 17.8.321(8) and (10) through (16).

We are proposing to disapprove the provisions of the Kraft Pulp Mill Rule found in ARM 17.8.321(9). We are also proposing to disapprove ARM 17.8.304(4)(f).

EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before we take final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to us as discussed in prior sections of this proposed rule.

V. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed 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 proposed action merely proposes to approve and disapprove state law as meeting and not meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed 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 proposes to approve and disapprove 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 proposed 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 proposes to approve and disapprove portions of a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed 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 Clean Air Act. 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 Clean Air Act. 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 proposed 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.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: June 4, 2008.

Carol Rushin,

Deputy Regional Administrator, Region 8.

[FR Doc. E8–14622 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 383, 384, 390, and 391

[Docket No. FMCSA–1997–2210]

RIN 2126–AA10

Medical Certification Requirements as Part of the Commercial Driver's License; Availability of Supplemental Document

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

ACTION: Proposed rule; availability of supplemental document.

SUMMARY: This notice advises the public that FMCSA is placing in the public docket an additional document that the Agency may rely on in support of a final rule to integrate information regarding the medical certification status of a driver into the commercial driver's license (CDL) process. FMCSA published a notice of proposed rulemaking (NPRM) on this matter on November 16, 2006. Because the involved state cost analysis document was completed after publication of the NPRM and subsequent public comment period, the Agency now dockets and invites comment on it.

DATES: Comments on the document are due by July 28, 2008.

ADDRESSES: You may submit comments, identified by docket number FMCSA–1997–2210, by one of the following methods: Internet, facsimile, regular mail, or hand delivery. Please do not submit the same comments by more than one method. FMCSA encourages use of the Federal eRulemaking portal. It provides the most efficient and timely method of receiving and processing your comments.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation; 1200 New Jersey Avenue, SE.; Washington, DC 20590–0001.
- *Hand Delivery:* Ground floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number (FMCSA–1997–2210) or Regulatory Identification Number (RIN 2126–AA10) for this action. Note that all comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided. Refer to the Privacy Act heading at *http://www.regulations.gov* for further information.

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 the Department of Transportation's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19476) or you may visit *http://DocketsInfo.dot.gov.*

Submitting Comments:

- You can find electronic submission and retrieval help and guidelines under the ''help'' section of the Web site.
- For notification that FMCSA received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments on line.
- All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address or on the Web site.
- Comments received after the comment closing date will be available in the docket and will be considered to the extent it is practical.

FMCSA will continue to put relevant information in the docket as it becomes available after the comment period closing date, and interested persons should continue to examine the docket for new material.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, FMCSA, Room W64–224, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. Telephone: (202) 366–4001. E-mail address: *FMCSAMedical@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: On November 16, 2006, FMCSA published an NPRM on how the Agency proposes to integrate information regarding the medical certification status of a driver of a commercial motor vehicle into the CDL process (71 FR 66723). This rulemaking is required by section 215 of the Motor Carrier Safety Improvement Act of 1999 (MCSIA) (Pub. L. 106–159, 113 Stat. 1767, December 9, 1999; set out as a note to 49 U.S.C. 31305).

For a full explanation of this proposal, please see the preamble to the NPRM. The docket for this rulemaking (FMCSA–1997–2210) contains the NPRM and all of the background information for this rulemaking, including comments.

This notice calls attention to an additional docketed document which was not used in developing the NPRM that FMCSA may rely on in support of its final rule. Placing this document in the docket now is necessary because it only became available after the NPRM was published and after conclusion of the comment period established in the NPRM.

The Agency has placed the state cost analysis document referenced below in the docket for this rulemaking and will accept comments on this document until July 28, 2008.

The document that FMCSA is placing in the docket is titled: State Cost Analysis to Implement Notice of Proposed Rulemaking (NPRM) dated November 16, 2006 titled ''Medical Certification Requirements as Part of the CDL,'' prepared for the U.S. Department of Transportation by the North American Driver Safety Foundation, October 2007. Several States asserted in their comments to the NPRM that they believe the Agency underestimated State costs for complying with the proposed rule. They requested FMCSA to gather additional data from States on the anticipated costs for this proposal. In response, the Agency arranged to survey a sample of nine States to evaluate whether the costs to States to implement this rule would be different than those used in the NPRM. This report describes what cost information was collected and how that additional cost information was analyzed to better estimate the national costs of implementing the requirements outlined in the NPRM.

Issued on: June 20, 2008.

John H. Hill,

Administrator.

[FR Doc. E8–14608 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–EX–P

Notices

Federal Register

Vol. 73, No. 125

Friday, June 27, 2008

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

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

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

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* July 27, 2008.

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 CONTACT: Kimberly M. Zeich, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@jwod.gov.*

SUPPLEMENTARY INFORMATION: On April 25, May 2 and May 9, 2008 the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (73 FR 22324; 24219; 26363) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services and impact of the additions on the current or most recent contractors, the Committee has determined that the services 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 services to the Government.

2. The action will 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 addition to the Procurement List.

End of Certification

Accordingly, the following services are added to the Procurement List:

Services

Service Type/Location: Custodial & Grounds Maintenance, U.S. Federal Building and Courthouse—St. Croix, 3013 Estate Golden Rock, Christiansted, U.S. Virgin Islands.
NPA: The Corporate Source, Inc., New York, NY.
Contracting Activity: General Services Administration, Caribbean Property Management Center, Hato Rey, PR.

Service Type/Location: Mailroom Operations, Internal Revenue Service, 10715 David Taylor Drive, Charlotte, NC.
NPA: Employment Source, Inc., Fayetteville, NC.
NPA: ServiceSource, Inc., Alexandria, VA (prime contractor).
Contracting Activity: U.S. Department of the Treasury, Internal Revenue Service Headquarters, Oxon Hill, MD.

Service Type/Location: Laundry Refurbishment Services, Billings Fire Cache, 551 Northview Drive, Billings, MT.
NPA: Community Option Resource Enterprises, Inc., Billings, MT.
Contracting Activity: U.S. Department of the Interior, Bureau of Land Management—Montana State Office, Billings, MT.

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Patrick Rowe,

Deputy Executive Director.

[FR Doc. E8–14628 Filed 6–26–08; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

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

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List services to be performed by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must be Received On or Before: July 27, 2008.

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: Kimberly M. Zeich, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@AbilityOne.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 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 services to the Government.

2. If approved, the action will 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 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 services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Custodial Services. Grand Prairie Army Reserve Complex, Buildings 7900; 8070 and 8100, Grand Prairie, TX.
NPA: Goodwill Industrial Services of Fort Worth, Inc., Fort Worth, TX.
Contracting Activity: Army Reserve Contracting Center, 90th Regional Support Command, North Little Rock, AR.
Service Type/Location: Custodial Services. Illinois Military Academy, 1301 North MacArthur Blvd, Springfield, IL.
NPA: United Cerebral Palsy of the Land of Lincoln, Springfield, IL.
Contracting Activity: Illinois National Guard—Camp Lincoln, Springfield, IL.
Service Type/Location: Warehousing & Distribution Service. Naval Base Kitsap—Fleet and Industrial Supply Center (FISC), Bremerton, WA.
Service Type/Location: Warehousing & Distribution Service. Navy Undersea Warfare Center (NUWC) Division, Keyport, WA.
Service Type/Location: Warehousing & Distribution Service. Puget Sound Naval Shipyard (PSNS) and Intermediate Maintenance Facility (IMF) Submarine Base, Bangor, WA.
NPA: Skookum Educational Programs, Bremerton, WA.
Contracting Activity: Fleet and Industrial Supply Center, Bremerton, WA.
Service Type/Location: Custodial Services. US Coast Guard, Industrial Support Detachment (ISD) Building, 110 Mount Elliott Street, Detroit, MI.
NPA: New Horizons Rehabilitation Services, Inc., Auburn Hills, MI.
Contracting Activity: Department of Homeland Security, U.S. Coast Guard—Integrated Support Command (ISC), Cleveland, OH.
Service Type/Location: Medical Transcription. VA Southern Nevada Healthcare System, 2455 West Cheyenne Avenue, Las Vegas, NV.
NPA: National Telecommuting Institute, Inc., Boston, MA.
Contracting Activity: Department of Veterans Affairs, VISN 22 Network Business Center, Long Beach, CA.
Service Type/Location: Janitorial Services at Army/Navy Recruiting Office. Recruiting Station Army/Navy, 98–151 Pali Momi Street, Aiea, HI.
Service Type/Location: Janitorial Services at Air Force/Marine Corps Recruit. Recruiting Station 2, Air Force/Marine Corps, 98–151 Pali Momi Street, Aiea, HI.
Service Type/Location: Janitorial Services at Air Force Reserve Center. Recruiting Station 3 Air Force Reserve Center, 98–145 Kaonohi Street, Aiea, HI.
Service Type/Location: Janitorial Service at Army/Navy/Marines/AF Recruiting. Recruiting Station 4 Army/Navy/Marines/AF, 45–480 Kaneohe Bay Drive, Kaneohe, HI.
Service Type/Location: Janitorial Services at Army Recruiting Office. Recruiting Station 5 Army, 95–1249 Meheula Parkway, Mililani, HI.
NPA: Goodwill Contract Services of Hawaii, Inc., Honolulu, HI.
Contracting Activity: U.S. Army Engineering Division, Contracting Division, Honolulu, HI.

Patrick Rowe,
Deputy Executive Director.

[FR Doc. E8–14627 Filed 6–26–08; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: International Trade Administration (ITA).
Title: Steel Import License.
Form Number: ITA–4141P.
OMB Control Number: 0625–0245.
Type of Request: Regular submission.
Burden Hours: 100,000.
Number of Respondents: 3,500.
Average Hours per Response: 10 minutes.

Needs and Uses: In order to effectively monitor steel imports, the Department of Commerce must collect and provide timely aggregated summaries about these imports. The Steel Import License, proposed by the ITA/Import Administration, is the tool used to collect the necessary information. The Census Bureau currently collects steel import data and disseminates aggregate information, however, this process can take up to 90 days after importation of the product, giving interested parties and the public far less time to respond to injurious sales. The license process provides real-time information to the public which allows more time to address injurious sales.

Affected Public: Business and other for-profit organizations.

Frequency: On occasion.
Respondent's Obligation: Required to obtain or retain a benefit.
OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Fax number (202) 395–7285 or via the Internet at *David_Rostker@omb.eop.gov*.

Dated: June 24, 2008.

Gwellnar Banks,
Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–14593 Filed 6–26–08; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Notice of Invention Available for Licensing

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of Invention Available for Licensing.

SUMMARY: The invention listed below is owned in whole by the U.S. Government, as represented by the Secretary of Commerce. The U.S. Government's interest in this invention is available for licensing in accordance with 35 U.S.C. 207 and 37 CFR 404 to achieve expeditious commercialization of results of federally funded research and development.

FOR FURTHER INFORMATION CONTACT: Technical and licensing information on this invention may be obtained by writing to: National Institute of Standards and Technology, Office of Technology Partnerships, Attn: Mary Clague, Building 222, Room A240, Gaithersburg, MD 20899. Information is also available via telephone: 301–975–4188, fax 301–975–3482, or e-mail: *mary.clague@nist.gov.* Any request for information should include the NIST Docket number and title for the invention as indicated below.

SUPPLEMENTARY INFORMATION: NIST may enter into a Cooperative Research and

Development Agreement (''CRADA'') with the licensee to perform further research on the invention for purposes of commercialization. The invention available for licensing is:

[NIST Docket Number: 06–011]

Title: Gradient Elution Moving Boundary Electrophoresis (GEMBE).

Abstract: GEMBE is a method for performing electrophoretic separation and/or purification of compounds in a mixture. The essence of the invention is the use of a variable bulk flow in electrophoresis. The method uses the electrophoretic migration of chemical species in solution in combination with variable hydrodynamic bulk flow of the solution through a separation capillary or microfluidic channel. GEMBE can be used with the bulk flow solution flow in either direction with respect to the electrophoretic driving force. Continuous sample introduction eliminates the need for a sample injection mechanism, allowing for significant miniaturization.

Dated: June 18, 2008.

Richard F. Kayser,

Chief Scientist.

[FR Doc. E8–14635 Filed 6–26–08; 8:45 am]

BILLING CODE 3510–10–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Marine Debris Survey in the Coastal North Carolina Region

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 August 26, 2008.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Shay Viehman, 252–728–8744 or *shay.viehman@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

NOAA National Ocean Service's (NOS) Center for Coastal Fisheries and Habitat Research (CCFHR) has received funding from the NOAA Marine Debris Program to assess perceptions of marine debris (including derelict fishing gear) occurrence and distribution, environmental impacts, potential causes, and suggestions for reduction. The statutory authorities supporting this research are the Marine Debris Research, Prevention, and Reduction Act of 2006 (33 U.S.C. 1951 *et seq.*), and the Coastal Zone Management Act of 1972 (16 U.S.C. 1455).

NOS CCFHR requests information from fishermen holding either a commercial fishing license or a license for recreational fishermen to use commercial fishing gear issued by the State of North Carolina who fish in Core and Back Sounds. Upon receipt, this information will help determine the status of marine debris within Core and Back Sounds, North Carolina.

II. Method of Collection

Person-to-person survey technique.

III. Data

OMB Control Number: None.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations; individuals or households.

Estimated Number of Respondents: 200.

Estimated Time per Response: 25 minutes.

Estimated Total Annual Burden Hours: 83.

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: June 24, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–14592 Filed 6–26–08; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XI65

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Receipt of application for research permit (1414) and request for comment.

SUMMARY: Notice is hereby given that NMFS has received an application for scientific research from East Bay Municipal Utility District (EBMUD) in Lodi, CA. The permit would affect the federally threatened Central Valley steelhead Distinct Population Segment (DPS), as identified in the **SUPPLEMENTARY INFORMATION** section. This document serves to notify the public of the availability of the permit application for review and comment.

DATES: Written comments on the permit application must be received no later than 5 p.m. Pacific Standard Time on July 18, 2008.

ADDRESSES: Written comments on the permit application should be sent to the appropriate office. Comments may also be sent via fax to the number indicated for the request. Comments will not be accepted if submitted via e-mail or the Internet. The applications and related documents are available for review by appointment, for permit 1414: Protected Resources Division, NMFS, 650 Capitol Mall, Suite 8–300, Sacramento, CA 95814 (ph: 916–930–3600, fax: 916–930–3629). Documents may also be reviewed by appointment in the Office of Protected Resources, F/PR3, NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3226 (301–713–1401).

FOR FURTHER INFORMATION CONTACT: Shirley Witalis at phone number 916–930–3606, or e-mail: *Shirley.Witalis@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Authority

Issuance of permits and permit modifications, as required by the Endangered Species Act of 1973 (16 U.S.C. 1531–1543) (ESA), is based on a finding that such permits/modifications: (1) are applied for in good faith; (2) would not operate to the disadvantage of the listed species which are the subject of the permits; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA. Authority to take listed species is subject to conditions set forth in the permits. Permits and modifications are issued in accordance with and are subject to the ESA and NMFS regulations governing listed fish and wildlife permits (50 CFR parts 222–226).

Those individuals requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). The holding of such a hearing is at the discretion of the Assistant Administrator for Fisheries, NOAA. All statements and opinions contained in the permit action summaries are those of the applicant and do not necessarily reflect the views of NMFS.

Species Covered in This Notice

This notice is relevant to federally threatened Central Valley steelhead (*Oncorhynchus mykiss*).

Application Received

EBMUD requests a five-year permit (1414) to conduct monitoring and research of anadromous (Central Valley steelhead) and resident fishes in the Lower Mokelumne River. The goals of the project include measuring the success of the Lower Mokelumne River Restoration Program and determining if the modifications of the Lower Mokelumne River Project are appropriate for conserving fish and wildlife resources in the Lower Mokelumne River. Data will also be collected for developing a Hatchery and Genetics Management Plan for the Mokelumne River Fish Hatchery steelhead artificial propagation program. EBMUD's monitoring and research will consists of trapping, sampling, measuring, weighing and tagging fish, fish carcass surveying, and collecting *O. mykiss* tissue samples.

Dated: June 23, 2008.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E8–14648 Filed 6–26–08; 8:45 am]

BILLING CODE 3510–22–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Amendment to the 2008 Tariff Preference Level (TPL) for Nicaragua under the Central America-Dominican Republic-United States Free Trade Agreement (CAFTA-DR)

June 23, 2008.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Amending the 2008 TPL for Nicaragua.

EFFECTIVE DATE: June 27, 2008.

SUMMARY: This notice reduces the 2008 TPL for Nicaragua to 87,897,046 square meters equivalent to account for the shortfall in meeting the one-to-one commitment for cotton and man-made fiber woven trousers exported from Nicaragua to the United States.

FOR FURTHER INFORMATION CONTACT: Richard Stetson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Annex 3.28 of the CAFTA-DR; Section 1634(a)(2) and (c)(2) of the Pension Protection Act of 2006 (P.L. 109-280); Presidential Proclamation 8111 of February 28, 2007.

BACKGROUND:

Annex 3.28 of the CAFTA-DR establishes a TPL for non-originating apparel goods of Nicaragua. Section 1634(a)(2) of the Pension Protection Act references the exchange of letters between the United States and Nicaragua, which establishes the one-to-one commitment for cotton and man-made fiber trousers. Section 1634(c)(2) of the Pension Protection Act authorizes the President to proclaim a reduction in the overall limit in the TPL if the President determines that Nicaragua has failed to comply with the one-to-one commitment. In Presidential Proclamation 8111, the President delegated to CITA the authority to determine whether Nicaragua had failed to comply with the one-to-one commitment and to reduce the overall limit in the TPL.

In an exchange of letters dated March 24 and 27, 2006, Nicaragua agreed that for each square meter equivalent of exports of cotton and man-made fiber woven trousers entered under the TPL, Nicaragua would export to the United States an equal amount of cotton and man-made fiber woven trousers made of U.S. formed fabric of U.S. formed yarn. This commitment for cotton woven trousers applies to the first 30 million square meters equivalent in 2007, the second year after the date of entry into force of the CAFTA-DR. Further, any shortfall in meeting this commitment that was not rectified by April 1 of the succeeding year would be applied against the TPL for the succeeding year. For 2007, the shortfall in meeting the one-to-one commitment is 12,102,954 square meters equivalent. This amount is being deducted from the 2008 TPL, resulting in a new TPL level for 2008 of 87,897,046 square meters equivalent.

R. Matthew Priest,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. E8–14638 Filed 6–26–08; 8:45 am]

BILLING CODE 3510–DS–S

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review, Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), has submitted a public information collection request (ICR) entitled the AmeriCorps*VISTA Project Progress Report (OMB Control Number 3045–0043) 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). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Mr. Craig Kinnear at (202) 606–9708. Individuals who use a telecommunications device for the deaf (TTY–TDD) may call (202) 565–2799 between 8:30 a.m. and 5 p.m. eastern time, Monday through Friday.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Katherine Astrich, OMB Desk Officer for the Corporation

for National and Community Service, by any of the following two methods within 30 days from the date of publication in this **Federal Register**:

(1) By fax to: (202) 395–6974, Attention: Ms. Katherine Astrich, OMB Desk Officer for the Corporation for National and Community Service; and (2) Electronically by e-mail to: *Katherine_T._Astrich@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: 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 Corporation, 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;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Comments

A 60-day public comment Notice was published in the **Federal Register** on March 4, 2008. This comment period ended May 4, 2008. No public comments were received from this notice.

Description

The Progress Report (PPR) was designed to assure that AmeriCorps*VISTA sponsors address and fulfill legislated program purposes, meet agency program management and grant requirements, and assess progress toward project plan goals agreed upon in the signing of the Memorandum of Agreement.

The Corporation seeks to revise the previously used Project Application to: (a) Better align the information requested on the Concept Paper and the Application; and (b) simplify the project plan while continuing to provide a robust tool for evaluating project performance.

The Corporation seeks to revise the previously used PPR to: (a) Reduce respondent burden; (b) enhance data elements collected via this information collection tool; (c) establish reporting periods consistent with the Corporation's integrated grants management and reporting policies.

The current PPR is used by AmeriCorps*VISTA sponsors and grantees to report progress toward accomplishing work plan goals and objectives, reporting actual outcomes related to self-nominated performance measures meeting challenges encountered, describing significant activities, and requesting technical assistance. The PPR is also used to collect demographic data elements used by the Corporation for aggregate reporting purposes. Submissions of the PPR are done quarterly.

The revised PPR will be divided into two separate parts in order to reduce burden and to increase data integrity. All demographic data elements will be removed from the quarterly submissions and added to an annual VISTA Progress Report Supplement (VPRS) due 30 days after the end of a fiscal year. The quarterly reports will retain their purpose of providing monitoring and oversight of individual projects, while the annual data collection will serve the purpose of aggregate performance reporting for the VISTA program. Burden will be reduced by collecting the demographic data elements once a year instead of quarterly. Data integrity will be increased by tying data elements to specific fiscal years rather than project reporting cycles.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: AmeriCorps*VISTA Project Progress Report (PPR).

OMB Number: 3045–0043.

Agency Number: None.

Affected Public: AmeriCorps*VISTA sponsoring organizations.

PPR (Part A):

Total Respondents: 1000.

Frequency: Quarterly.

Average Time per Response: 7 hours.

Estimated Total Burden Hours: 28,000 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

VPRS (Part B):

Total Respondents: 1000.

Frequency: Annual.

Average Time Per Response: 8 hours.

Estimated Total Burden Hours: 8000 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: June 23, 2008.

Jean Whaley,

*Director, AmeriCorps*VISTA.*

[FR Doc. E8–14629 Filed 6–26–08; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Public Hearings for the Jacksonville Range Complex Draft Environmental Impact Statement/ Overseas Environmental Impact Statement

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969 (42 United States Code [U.S.C.] § 4321); the Council of Environmental Quality (CEQ) Regulations for implementing the procedural provisions of NEPA (Title 40 Code of Federal Regulations [CFR] Parts 1500–1508); Department of the Navy Procedures for Implementing NEPA (32 CFR 775); Executive Order (EO) 12114, Environmental Effects Abroad of Major Federal Actions; and Department of Defense (DoD) regulations implementing EO 12114 (32 CFR Part 187), the Department of the Navy (Navy) has prepared and filed with the U.S. Environmental Protection Agency a Draft Environmental Impact Statement/ Overseas Environmental Impact Statement (EIS/OEIS) on June 18, 2008. The National Marine Fisheries Service (NMFS) is a Cooperating Agency for the EIS/OEIS.

The EIS/OEIS evaluates the potential environmental impacts over a 10-year planning horizon associated with Navy Atlantic Fleet training; research, development, testing, and evaluation (RDT&E) activities; and associated range capabilities enhancements (including infrastructure improvements) within the existing Jacksonville (JAX) Range Complex Operating Area (OPAREA). The JAX Range Complex geographically encompasses offshore, near-shore, and onshore OPAREA, ranges, and special use airspace (SUA).

Components of the JAX Range Complex encompass 50,090 square nautical miles (nm^2) of sea space and 62,596 nm^2 of SUA off the coasts of North Carolina, South Carolina, Georgia, and Florida, as well as 20 $miles^2$ of inland range area in north-central Florida. A Notice of Intent for this Draft EIS/OEIS was published in the **Federal Register** on January 26, 2007 (72 FR 3806).

The Navy will conduct four public hearings to receive oral and written comments on the Draft EIS/OEIS. Federal agencies, state agencies, and local agencies and interested individuals are invited to be present or represented at the public hearings. This notice announces the dates and locations of the public hearings for this Draft EIS/OEIS.

An open house session will precede the scheduled public hearing at each of the locations listed below and will allow individuals to review the information presented in the JAX Range Complex Draft EIS/OEIS. Navy representatives will be available during the open house sessions to clarify information related to the Draft EIS/OEIS.

DATES AND ADDRESSES: All meetings will start with an open house session from 5 p.m. to 7 p.m. A formal presentation and public comment period will be held from 7 p.m. to 9 p.m. Public hearings will be held on the following dates and at the following locations: July 28, 2008 at the Doubletree Guest Suites—Historic Charleston, 181 Church Street, Charleston, SC; July 29, 2008 at the Holiday Inn Beaufort; 2225 Boundry St., Beaufort, SC; July 30, 2008 at the Hyatt Regency Savannah, 2 W. Bay Street, Savannah, GA; July 31, 2008 at the Hyatt Regency Jacksonville—Riverfront; 225 E. Coastline Dr., Jacksonville, FL.

FOR FURTHER INFORMATION CONTACT: Naval Facilities Engineering Command, Atlantic, Attention, EV22CM (JAX EIS/OEIS PM), 6506 Hampton Boulevard, Norfolk, Virginia 23508–1278; facsimile: 757–322–4894 or *http://www.jacksonvillerangecomplexeis.com.*

SUPPLEMENTARY INFORMATION: The Navy has identified the need to support and conduct current and emerging training and RDT&E operations in the JAX Range Complex. The proposed action does not indicate major changes to JAX Range Complex facilities, operations, training, or RDT&E capacities over the 10-year planning period. Rather, the proposed action would result in relatively small-scale but critical enhancements to the JAX Range Complex that are necessary if the Navy is to maintain a state of military readiness commensurate with its national defense mission.

The EIS/OEIS addresses the training strategies described in the Fleet Readiness Training Plan (FRTP) that implement the Fleet Response Plan, which ensures continuous availability of agile, flexible, trained, and ready surge-capable (rapid response) forces. The recommended range enhancements that have the potential to impact the environment, as well as current and future training and testing operations that have the potential to impact the environment, are the primary focus of the EIS/OEIS.

The purpose for the proposed action is to:

- Achieve and maintain Fleet readiness using the JAX Range Complex to support and conduct current, emerging, and future training operations and RDT&E operations;
- Expand warfare missions supported by the JAX Range Complex; and
- Upgrade and modernize existing range capabilities to enhance and sustain Navy training and RDT&E.

The need for the proposed action is to provide range capabilities for training and equipping combat-capable naval forces ready to deploy worldwide. In this regard, the JAX Range Complex furthers the Navy's execution of its Congressionally mandated roles and responsibilities under Title 10 U.S.C. § 5062. To implement this Congressional mandate, the Navy needs to:

- Maintain current levels of military readiness by training in the JAX Range Complex;
- Accommodate future increases in operational training tempo in the JAX Range Complex and support the rapid deployment of naval units or strike groups;
- Achieve and sustain readiness of ships and squadrons so the Navy can quickly surge significant combat power in the event of a national crisis or contingency operation, and consistent with the FRTP;
- Support the acquisition and implementation into the Fleet of advanced military technology. The JAX Range Complex must adequately support the testing and training needed for new platforms (aircraft and weapons systems); and
- Maintain the long-term viability of the JAX Range Complex while protecting human health and the environment, and enhancing the quality and communication capability and safety of the range complex.
- Support to current, emerging, and future training and RDT&E operations, including implementation of range enhancements, entails the actions evaluated in the EIS/OEIS.

These potentially include:

- Increase use of contractor-operated small aircraft that simulate enemy aircraft during training (Commercial Air Services Support for Fleet Opposition Forces and Electronic Warfare Threat Training);
- Increase anti-piracy and maritime interdiction training (Anti-terrorism Surface Strike Group Training);
- Support MH–60R helicopter warfare mission areas, and Multi-Mission Maritime Aircraft training operations; and
- Conduct mine warfare training using a temporary mine training area.

The proposed action is to support and conduct current and emerging training and RDT&E operations in the JAX Range Complex. To achieve this, the Navy proposes to:

- Maintain training and RDT&E operations at current levels if the No Action Alternative is selected.

If either Alternative 1 or Alternative 2 is selected, then:

- Increase or modify training and RDT&E operations from current levels as necessary in support of the FRTP.
- Accommodate mission requirements associated with force structure changes, including those resulting from the introduction of new platforms (aircraft, and weapons systems).
- Implement enhanced range complex capabilities.

The decision to be made by the Assistant Secretary of the Navy (Installations & Environment) is to determine which alternative analyzed in the EIS/OEIS satisfies both the level and mix of training to be conducted and the range capabilities enhancements to be made within the JAX Range Complex that best meet the needs of the Navy given that all reasonably foreseeable environmental impacts have been considered.

Three alternatives were evaluated in the EIS/OEIS to ensure they met the purpose and need, giving due consideration to range complex attributes such as: The capability to support current and emerging Fleet tactical training and RDT&E requirements; the capability to support realistic, essential training at the level and frequency sufficient to support the FRTP; and the capability to support training requirements while following Navy Personnel Tempo of Operations guidelines. These alternatives include:

1. The No Action Alternative—Current Operations to include surge consistent with the FRTP;

2. Alternative 1—No Action Alternative plus: increase Operational Training, Expand Warfare Missions, Accommodate Force Structure Changes (includes changing weapon systems and platforms and homebasing new aircraft and ships), and implement enhancements, to the minimal extent possible to meet the components of the proposed action. This alternative is composed of all operations currently conducted (No Action Alternative) with modifications to current training or

introduction of new training. These would include: (a) Using more commercial aircraft to serve as oppositional forces rather than using Navy aircraft for Air-to-Air Missile Exercise, Surface-to-Air Gunnery Exercises, Air Intercept Control Exercises, and Detect-to-Engage Exercises; (b) the incorporation of anti-terrorism training into existing training events; (c) adjusting training levels to ensure that deployment can be stepped up quickly and at multiple locations in response to world events; and (d) conducting new or modified training associated with the introduction of the new MH–60 helicopter, and new organic mine countermeasure systems; and

3. Alternative 2 (Preferred Alternative)—Alternative 1 plus: additional mine warfare training capabilities, and implementation of additional enhancements to enable the range complex to meet future requirements.

Three alternatives were considered but eliminated from further consideration. These alternatives are:

1. Alternative Range Complex Locations—No single range complex on the East Coast can accommodate the entire spectrum of Navy and Marine Corps training and testing. To maintain a high level of combat readiness for naval forces at best value to the U.S. taxpayer, the Navy and Marine Corps homeported their forces in multiple concentration areas rather than a single area, in part to ensure the surrounding training and testing areas could support their specific needs. The result is a system of range complexes, each optimized to support the limited set of warfare areas that predominate in that locale. The JAX Range Complex possesses a number of historical and natural features that make it an indispensable component of the Navy's East Coast system of ranges. The JAX Range Complex is a vital component of the Atlantic Fleet system of range complexes, necessary and critical to ensure that naval forces are prepared and certified ready for overseas deployment and combat operations. Other locations do not provide reasonable alternatives for required training purposes/activities described above, and as a result, alternative training locations were eliminated from further consideration.

2. Conduct Simulated Training Only—Under this alternative, only simulated training would be conducted using computer models and classroom training. While computer simulation and classroom training are currently used by the Navy and effective training tools, they cannot exclusively replace live training because they do not replicate the atmosphere or experience that live training provides. Simulation cannot replicate the environment that is provided during coordinated training and major exercises, where multiple ships, submarines and aircraft, and hundreds or thousands of men and women are participating in training activities in a coordinated fashion to accomplish a common military objective. Because of the need to train as we fight, this alternative would fail to meet the purpose and need of the proposed action in that it would not sufficiently prepare our naval forces for combat. Therefore, this alternative is not evaluated in the EIS/OEIS.

3. Practice Ammunition Use—An alternative that would rely entirely on inert, practice ammunition use within the JAX Range Complex would not achieve the necessary levels of proficiency in firing weapons in a high stress and realistic environment. Inert, practice ammunition is utilized throughout the JAX Range Complex, and provides opportunity to implement a successful, integrated training program while reducing the risk and expense typically associated with live ammunition. As such, practice ammunition is already utilized extensively to enhance combat performance in the Navy's training program. However, while it is an essential component of training, practice ammunition cannot be used exclusively to train safely in an inherently unsafe combat environment. Consequently, this alternative fails to meet the purpose and need of the proposed action. Therefore, this alternative was not carried forward for analysis.

Twenty resources and issues were described and analyzed in the EIS/OEIS. These include but are not limited to water resources, air quality, marine communities, marine mammals, sea turtles, fish and essential fish habitat, seabirds and migratory birds, cultural resources, regional economy, and public health and safety. The Navy used subject matter experts, public and agency scoping comments, previous environmental analyses, previous agency consultations, laws, regulations, Executive Orders and resource-specific information in a screening process to identify aspects of the proposed action that could act as stressors to resources and issues evaluated in the EIS/OEIS.

The stressors considered for analysis of environmental consequences include but are not limited to vessel movements (disturbance and collisions), aircraft overflights (disturbance and strikes), non-explosive practice munitions, and underwater detonations and high explosive ordnance.

In accordance with 50 CFR § 401.12, the Navy submitted a Biological Evaluation to assess the potential effects from the proposed action on marine resources and anadromous fish protected by the NMFS under the Endangered Species Act (ESA). In accordance with the Marine Mammal Protection Act MMPA (16 U.S.C. § 1371[a][5]), the Navy submitted a request for Letter of Authorization to the NMFS for the incidental taking of marine mammals by the proposed action which was acknowledged by NMFS in a Notice of Receipt published in the **Federal Register** (Vol. 73, No. 72, pp. 20032–20034) on April 14, 2008.

The Navy submitted a Consultation Package in accordance with legal requirements set forth under regulations implementing section 7 of the ESA (50 CFR 402; 16 U.S.C 1536(c)) for listed species under jurisdiction of the U.S. Fish and Wildlife Service. The analysis of environmental stressors indicated that implementation of the No Action Alternative, Alternative 1, or Alternative 2 would not result in unavoidable significant adverse effects to resources analyzed. The analysis of environmental stressors and alternatives indicated no significant impact to resources in U.S. territorial waters; likewise, no significant harm in non-territorial waters are expected.

The JAX Draft EIS/OEIS was distributed to Federal, State, and local agencies, elected officials, and other interested individuals and organizations on June 27, 2008. The public comment period will end on August 11, 2008. Copies of the JAX Draft EIS/OEIS are available for public review at the following libraries: Charleston County Library, 68 Calhoun Street; Charleston, SC; Beaufort County Public Library, 311 Scott Street, Beaufort, SC; Live Oak Public Libraries, 2002 Bull Street, Savannah, GA; Three Rivers Regional Library System, 208 Gloucester Street, Brunswick, GA; Jacksonville Public Library, 303 North Laura Street, Jacksonville, FL; Polk County Library Cooperative, 215 South Bougainvillea Avenue, Polk City, FL; and Marion County Public Library, 2720 East Silver Springs Boulevard, Ocala, FL.

The JAX Draft EIS/OEIS is also available for electronic public viewing at *http://www.jacksonvillerangecomplexeis.com.* A paper copy of the Executive Summary or a single CD with the JAX Draft EIS/OEIS will be made available upon written request by contacting Naval Facilities Engineering Command,

Atlantic Division; Attention: Code EV22CM (JAX EIS/OEIS PM); 6506 Hampton Blvd.; Norfolk, VA 23508–1278. Facsimile: 757–322–4894. Federal, State, and local agencies and interested parties are invited to be present or represented at the public hearing. Written comments can also be submitted during the open house sessions preceding the public hearings.

Oral statements will be heard and transcribed by a stenographer; however, to ensure the accuracy of the record, all statements should be submitted in writing. All statements, both oral and written, will become part of the public record on the Draft EIS/OEIS and will be responded to in the Final EIS/OEIS. Equal weight will be given to both oral and written statements. In the interest of available time, and to ensure all who wish to give an oral statement have the opportunity to do so, each speaker's comments will be limited to three (3) minutes. If a long statement is to be presented, it should be summarized at the public hearing with the full text submitted either in writing at the hearing, or mailed or faxed to Naval Facilities Engineering Command, Atlantic Division; Attention: Code EV22CM (JAX EIS/OEIS PM); 6506 Hampton Blvd.; Norfolk, VA 23508–1278. Facsimile: 757–322–4894. In addition, comments may be submitted on-line at *http://www.jacksonvillerangecomplexeis.com* during the comment period. All written comments must be postmarked by August 11, 2008 to ensure they become part of the official record. All comments will be addressed in the Final EIS/OEIS.

Dated: June 23, 2008.

T.M. Cruz,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–14541 Filed 6–26–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Public Hearings for the Virginia Capes Range Complex Draft Environmental Impact Statement/ Overseas Environmental Impact Statement

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969 (42 United States Code [U.S.C.] 4321); the Council of Environmental Quality (CEQ) Regulations for implementing the procedural provisions of NEPA (Title 40 Code of Federal Regulations [CFR] 1500–1508); Department of the Navy Procedures for Implementing NEPA (32 CFR 775); Executive Order (EO) 12114, Environmental Effects Abroad of Major Federal Actions; and Department of Defense (DoD) regulations implementing EO 12114 (32 CFR 187) the Department of the Navy (Navy) has prepared and filed with the U.S. Environmental Protection Agency a Draft Environmental Impact Statement/ Overseas Environmental Impact Statement (EIS/OEIS) on June 16, 2008. The National Marine Fisheries Service (NMFS) is a Cooperating Agency for the EIS/OEIS.

The EIS/OEIS evaluates the potential environmental impacts over a 10-year planning horizon associated with Navy Atlantic Fleet training; research, development, testing, and evaluation (RDT&E) activities; and associated range capabilities enhancements (including infrastructure improvements) within the existing Virginia Capes (VACAPES) Range Complex Operating Area (OPAREA). The components of the VACAPES Range Complex include 28,672 square nautical miles (nm^2) of special use area (SUA) warning area; 27,661 nm^2 of offshore surface and subsurface OPAREA; and 18,092 nm^2 of deep ocean area greater than 100 fathoms (600 feet).

The geographic scope of the EIS/OEIS includes the airspace, seaspace, and undersea space of the VACAPES Range Complex. This area is referred to as the VACAPES Study Area. The VACAPES Study Area does not include any dry land. However, it does include the area from the mean high tide line east (seaward) to the 3nm boundary of the states of Delaware, Maryland, Virginia, and North Carolina. This 3-nm state boundary also serves as the western boundary of the VACAPES OPAREA. The VACAPES Study Area also includes 420 nm^2 of the lower Chesapeake Bay. A Notice of Intent (NOI) for the EIS/ OEIS was published in the **Federal Register** on December 8, 2006 (**Federal Register** Volume 71, No. 236, pp 71143–71145). A revised NOI was issued in the **Federal Register** (Volume 72, No. 171, pp 50940–50941) on September 5, 2007 when training areas in the southern Chesapeake Bay were identified for analysis.

The Navy will conduct four public hearings to receive oral and written comments on the Draft EIS/OEIS. Federal agencies, state agencies, and local agencies and interested individuals are invited to be present or represented at the public hearings. This notice announces the dates and locations of the public hearings for this Draft EIS/OEIS.

An open house session will precede the scheduled public hearing at each of the locations listed below and will allow individuals to review the information presented in the VACAPES Range Complex Draft EIS/OEIS. Navy representatives will be available during the open house sessions to clarify information related to the Draft EIS/ OEIS.

DATES AND ADDRESSES: All meetings will start with an open house session from 5 p.m. to 7 p.m. A formal presentation and public comment period will be held from 7 p.m. to 9 p.m. Public hearings will be held on the following dates and at the following locations: July 14, 2008 at the Princess Royale Oceanfront Hotel, 9100 Coastal Hwy., Ocean City, MD; July 15, 2008 at the Chincoteague Center, 6155 Community Dr., Chincoteague, VA; July 16, 2008 at the Virginia Beach Resort & Conference Ctr., 2800 Shore Dr., Virginia Beach, VA; and July 17, 2008 at the Hilton Garden Inn, 5353 N. Va. Dare Trail, Kitty Hawk, NC.

FOR FURTHER INFORMATION CONTACT: Naval Facilities Engineering Command, Atlantic, Attention, EV22ES (VACAPES EIS/OEIS PM), 6506 Hampton Boulevard, Norfolk, Virginia 23508–1278; facsimile: 757–322–4894 or *http://www.vacapesrangecomplexeis.com.*

SUPPLEMENTARY INFORMATION: The Navy has identified the need to support and conduct current and emerging training and RDT&E operations in the VACAPES Range Complex. The proposed action does not indicate major changes to VACAPES Range Complex facilities, operations, training, or RDT&E capacities over the 10-year planning period. Rather, the proposed action would result in relatively small-scale but critical enhancements to the VACAPES Range Complex that are necessary if the Navy is to maintain a state of military readiness commensurate with its national defense mission.

The EIS/OEIS addresses the training strategies described in the Fleet Readiness Training Plan (FRTP) that implement the Fleet Response Plan, which ensures continuous availability of agile, flexible, trained, and ready surge-capable (rapid response) forces. The recommended range enhancements that have the potential to impact the environment, as well as current and future training and testing operations that have the potential to impact the environment, are the primary focus of the EIS/OEIS.

The purpose for the proposed action is to:

• Achieve and maintain Fleet readiness using the VACAPES Range Complex to support and conduct current, emerging, and future training operations and RDT&E operations;

• Expand warfare missions supported by the VACAPES Range Complex; and

• Upgrade and modernize existing range capabilities to enhance and sustain Navy training and RDT&E.

The need for the proposed action is to provide range capabilities for training and equipping combat-capable naval forces ready to deploy worldwide. In this regard, the VACAPES Range Complex furthers the Navy's execution of its congressionally mandated roles and responsibilities under Title 10 U.S.C. 5062. To implement this Congressional mandate, the Navy needs to:

• Maintain current levels of military readiness by training in the VACAPES Range Complex;

• Accommodate future increases in operational training tempo in the VACAPES Range Complex and support the rapid deployment of naval units or strike groups;

• Achieve and sustain readiness of ships and squadrons so the Navy can quickly surge significant combat power in the event of a national crisis or contingency operation, and consistent with the FRTP;

• Support the acquisition and implementation into the Fleet of advanced military technology. The VACAPES Range Complex must adequately support the testing and training needed for new platforms (aircraft and weapons systems); and

• Maintain the long-term viability of the VACAPES Range Complex while protecting human health and the environment, and enhancing the quality and communication capability and safety of the range complex.

Support to current, emerging, and future training and RDT&E operations, including implementation of range enhancements, entails the actions evaluated in the EIS/OEIS. These potentially include:

• Increase use of contractor-operated small aircraft that simulate enemy aircraft during training (Commercial Air Services Support for Fleet Opposition Forces and Electronic Warfare Threat Training);

• Increase anti-piracy and maritime interdiction training (Anti-terrorism Surface Strike Group Training);

• Support MH–60R/S helicopter warfare mission areas, and Multi-Mission Maritime Aircraft training operations; and

• Conduct mine warfare training using a temporary mine training area.

The proposed action is to support and conduct current and emerging training and RDT&E operations in the VACAPES Range Complex. To achieve this, the Navy proposes to:

• Maintain training and RDT&E operations at current levels if the No Action Alternative is selected.

If either Alternative 1 or Alternative 2 is selected, then:

• Increase or modify training and RDT&E operations from current levels as necessary in support of the FRTP.

• Accommodate mission requirements associated with force structure changes, including those resulting from the introduction of new platforms (aircraft, and weapons systems).

• Implement enhanced range complex capabilities.

The decision to be made by the Assistant Secretary of the Navy (Installations & Environment) is to determine which alternative analyzed in the EIS/OEIS satisfies both the level and mix of training to be conducted and the range capabilities enhancements to be made within the VACAPES Range Complex that best meet the needs of the Navy given that all reasonably foreseeable environmental impacts have been considered.

Three alternatives were evaluated in the EIS/OEIS to ensure they met the purpose and need, giving due consideration to range complex attributes such as: the capability to support current and emerging Fleet tactical training and RDT&E requirements; the capability to support realistic, essential training at the level and frequency sufficient to support the FRTP; and the capability to support training requirements while following Navy Personnel Tempo of Operations guidelines. These alternatives include:

1. The No Action Alternative—Current Operations to include surge consistent with the FRTP;

2. Alternative 1—No Action Alternative plus: increase Operational Training, Expand Warfare Missions, Accommodate Force Structure Changes (includes changing weapon systems and platforms and homebasing new aircraft and ships), and implement enhancements, to the minimal extent possible to meet the components of the proposed action. This alternative is composed of all operations currently conducted (No Action Alternative) with modifications to current training or introduction of new training. These would include: (a) Using more commercial aircraft to serve as oppositional forces rather than using Navy aircraft for Air-to-Air Missile Exercise, Surface-to-Air Gunnery Exercises, Air Intercept Control Exercises, and Detect-to-Engage Exercises; (b) the incorporation of anti-terrorism training into existing training events; (c) adjusting training levels to ensure that deployment can be stepped up quickly and at multiple locations in response to world events; and (d) conducting new or modified training associated with the introduction of the new MH–60 helicopter, and new organic mine countermeasure systems; and

3. Alternative 2 (Preferred Alternative)—Alternative 1 plus: enhanced mine warfare training capabilities, a reduction of live bombing exercises, and implementation of additional enhancements to enable the range complex to meet future requirements.

Three alternatives were considered but eliminated from further consideration. These include:

1. Alternative Range Complex Locations—No single range complex on the East Coast can accommodate the entire spectrum of Navy and Marine Corps training and testing. To maintain a high level of combat readiness for naval forces at best value to the U.S. taxpayer, the Navy and Marine Corps homeported their forces in multiple concentration areas rather than a single area, in part to ensure the surrounding training and testing areas could support their specific needs. The result is a system of range complexes, each optimized to support the limited set of warfare areas that predominate in that locale. The VACAPES Range Complex possesses a number of historical and natural features that make it an indispensable component of the Navy's East Coast system of ranges. The VACAPES Range Complex is a vital component of the Atlantic Fleet system of range complexes, necessary and critical to ensure that naval forces are prepared and certified ready for overseas deployment and combat operations. Other locations do not provide reasonable alternatives for required training purposes/activities described above, and as a result, alternative training locations were eliminated from further consideration.

2. Conduct Simulated Training Only—Under this alternative, only simulated training would be conducted using computer models and classroom training. While computer simulation and classroom training are currently used by the Navy and effective training tools, they cannot exclusively replace live training because they do not replicate the atmosphere or experience

that live training provides. Simulation cannot replicate the environment that is provided during coordinated training and major exercises, where multiple ships, submarines and aircraft, and hundreds or thousands of men and women are participating in training activities in a coordinated fashion to accomplish a common military objective. Because of the need to train as we fight, this alternative would fail to meet the purpose and need of the proposed action in that it would not sufficiently prepare our naval forces for combat. Therefore, this alternative is not evaluated in the EIS/OEIS.

3. Practice Ammunition Use—An alternative that would rely entirely on inert, practice ammunition use within the VACAPES Range Complex would not achieve the necessary levels of proficiency in firing weapons in a high stress and realistic environment. Inert, practice ammunition is utilized throughout the VACAPES Range Complex, and provides opportunity to implement a successful, integrated training program while reducing the risk and expense typically associated with live ammunition. As such, practice ammunition is already utilized extensively to enhance combat performance in the Navy's training program. However, while it is an essential component of training, practice ammunition cannot be used exclusively to train safely in an inherently unsafe combat environment. Consequently, this alternative fails to meet the purpose and need of the proposed action. Therefore, this alternative was not carried forward for analysis.

Nineteen resources and issues were described and analyzed in the EIS/OEIS. These include but are not limited to water resources, air quality, marine communities, marine mammals, sea turtles, fish and essential fish habitat, seabirds and migratory birds, cultural resources, regional economy, and public health and safety. The Navy used subject matter experts, public and agency scoping comments, previous environmental analyses, previous agency consultations, laws, regulations, Executive Orders and resource-specific information in a screening process to identify aspects of the proposed action that could act as stressors to resources and issues evaluated in the EIS/OEIS.

The stressors considered for analysis of environmental consequences include but are not limited to vessel movements (disturbance and collisions), aircraft overflights (disturbance and strikes), non-explosive practice munitions, and underwater detonations and high explosive ordnance.

In accordance with 50 CFR 401.12 the Navy submitted a Biological Evaluation to assess the potential effects from the proposed action on marine resources and anadromous fish protected by the NMFS under the Endangered Species Act (ESA). In accordance with the Marine Mammal Protection Act MMPA (16 U.S.C. 1371[a][5]), the Navy submitted a request for Letter of Authorization to the NMFS for the incidental taking of marine mammals by the proposed action which was acknowledged by NMFS in a Notice of Receipt published in the **Federal Register** (Vol. 73, No. 72, pp 20032–20034) on April 14, 2008.

The Navy submitted a Consultation Package in accordance with legal requirements set forth under regulations implementing Section 7 of the ESA (50 CFR 402; 16 U.S.C 1536 (c)) for listed species under jurisdiction of the U.S. Fish and Wildlife Service. The analysis of environmental stressors indicated that implementation of the No Action Alternative, Alternative 1, or Alternative 2 would not result in unavoidable significant adverse effects to resources and issues analyzed.

The analysis of environmental stressors and alternatives indicated no significant impact to resources and issues in U.S. territorial waters; likewise, no significant harm in non-territorial waters would be expected. The VACAPES Draft EIS/OEIS was distributed to Federal, State, and local agencies, elected officials, and other interested individuals and organizations on June 27, 2008. The public comment period will end on August 11, 2008. Copies of the VACAPES Draft EIS/OEIS are available for public review at the following libraries: Ocean City Branch Library, 10003 Coastal Highway, Ocean City, MD; Rehoboth Beach Public Library, 226 Rehoboth Avenue Rehoboth Beach, DE; Wicomico Public Library, 122 South Division Street, Salisbury, MD; Island Library, 4077 Main Street, Chincoteague, VA; Central Library, 4100 Virginia Beach Blvd, Virginia Beach, VA; and Kill Devil Hills Branch Library, 400 S. Mustian St, Kill Devil Hills, NC.

The VACAPES Draft EIS/OEIS is also available for electronic public viewing at *http://www.vacapesrangecomplexeis.com.* A paper copy of the Executive Summary or a single CD with the VACAPES Draft EIS/OEIS will be made available upon written request by contacting Naval Facilities Engineering Command, Atlantic Division; Attention: Code EV22ES (VACAPES EIS/OEIS PM); 6506 Hampton Blvd; Norfolk, VA 23508–1278; facsimile: 757–322–4894. Federal, State, and local agencies and interested parties are invited to be present or represented at the public hearing. Written comments can also be submitted during the open house sessions preceding the public hearings. Oral statements will be heard and transcribed by a stenographer; however, to ensure the accuracy of the record, all statements should be submitted in writing. All statements, both oral and written, will become part of the public record on the Draft EIS/OEIS and will be responded to in the Final EIS/OEIS. Equal weight will be given to both oral and written statements.

In the interest of available time, and to ensure all who wish to give an oral statement have the opportunity to do so, each speaker's comments will be limited to three (3) minutes. If a long statement is to be presented, it should be summarized at the public hearing with the full text submitted either in writing at the hearing, or mailed or faxed to Naval Facilities Engineering Command, Atlantic Division; Attention: Code EV22ES (VACAPES EIS/OEIS PM); 6506 Hampton Blvd; Norfolk, VA 23508–1278; facsimile: 757–322–4894. In addition, comments may be submitted on-line at *http://www.vacapesrangecomplexeis.com* during the comment period. All written comments must be postmarked by August 11, 2008 to ensure they become part of the official record. All comments will be addressed in the Final EIS/OEIS.

Dated: June 18, 2008.

T.M. Cruz,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–14539 Filed 6–26–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Willow Creek Wind Project

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of Availability of Record of Decision (ROD).

SUMMARY: The Bonneville Power Administration (BPA) has decided to offer contract terms for the electrical interconnection into the Federal Columbia River Transmission System (FCRTS) of up to 72 megawatts of power to be generated by the proposed Willow Creek Wind Project (Wind Project). Willow Creek Energy, LLC proposes to construct and operate the proposed Wind Project in Gilliam and Morrow

counties, Oregon, and has requested interconnection to the FCRTS at a point along BPA's existing Tower Road-Alkali 115-kilovolt transmission line in Gilliam County, Oregon. BPA will construct a tap to allow the Wind Project to interconnect to BPA's transmission line, and will install new equipment at BPA's existing Boardman Substation in Morrow County, Oregon to accommodate this additional power in the FCRTS. This decision to interconnect the Wind Project is consistent with and tiered to BPA's Business Plan Final Environmental Impact Statement (DOE/EIS–0183, June 1995), and Business Plan ROD (August 1995).

ADDRESSES: Copies of this tiered ROD and the Business Plan EIS and ROD may be obtained by calling BPA's toll-free document request line, 1–800–622–4520. The RODs and EIS are also available on our Web site, *www.efw.bpa.gov.*

FOR FURTHER INFORMATION, CONTACT: Doug Corkran, Bonneville Power Administration—KEC–4, P.O. Box 3621, Portland, Oregon, 97208–3621; toll-free telephone number 1–800–622–4519; fax number 503–230–5699; or e-mail *dfcorkran@bpa.gov.*

Issued in Portland, Oregon, on June 4, 2008.

Stephen J. Wright,

Administrator and Chief Executive Officer.

[FR Doc. E8–14610 Filed 6–26–08; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8685–8]

Concepts, Methods, and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures, and Effects: A Resource Document

AGENCY: Environmental Protection Agency (U.S. EPA).

ACTION: Notice of Availability.

SUMMARY: The U.S. EPA announces the availability of a final document entitled, ''Concepts, Methods, and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures, and Effects: A Resource Document'' (EPA/600/R–06/013F), which was prepared by the National Center for Environmental Assessment (NCEA) within the U.S. EPA's Office of Research and Development (ORD).

This document represents a collaborative effort between the U.S. EPA and the U.S. Department of Energy (U.S. DOE) that is designed to serve as an interim resource between U.S. EPA's 2003 ''Framework for Cumulative Risk Assessment'' (EPA/630/P–02/001F) and future documents on approaches and guidance to cumulative risk assessment. The document provides concepts, methods, and data sources for consideration and possible use in the conduct of a cumulative risk assessment. Specifically, the document focuses on two areas: (1) Initiating factors for a cumulative risk assessment, with procedures for data collection and organization, and (2) technical approaches for assessing human health risks associated with a subset of cumulative risk issues (i.e., multiple chemicals, exposures, and effects). Overall, this document demonstrates the feasibility of including combinations of chemicals, exposures, effects and their interactions into a cumulative risk assessment and is meant to assist with the conduct of multi-chemical, population-focused assessments.

This document has undergone review within the U.S. EPA, independent external peer review by a panel of scientific experts, and it has also benefited from a 45-day public comment period. However, it has not undergone the scrutiny required of a guidance document and, thus, does not represent U.S. EPA policy.

DATES: This document will be available on or about June 26, 2008.

ADDRESSES: The document will be available electronically through the National Center for Environmental Assessment (NCEA) Web site at *http://www.epa.gov/ncea.* A limited number of paper copies will be available from the U.S. EPA's National Service Center for Environmental Publications (NSCEP); P.O. Box 42419; Cincinnati, OH 45242; (800) 490–9198 (telephone); (301) 604–3408 (facsimile); *nscep@bps-lmit.com.* Please provide your name, your mailing address, the title and the EPA number of the requested publication.

FOR FURTHER INFORMATION CONTACT: Linda K. Teuschler, Project Leader, NCEA-Cin; 26 W. Martin Luther King Dr. (A–G20); Cincinnati, OH 45268; (513) 569–7573 (telephone); (513) 487–2539 (fax); *teuschler.linda@epa.gov.*

SUPPLEMENTARY INFORMATION: The U.S. EPA's 2003 ''Framework for Cumulative Risk Assessment'' and earlier reports from the 1990s on the initial planning and scoping phase needed to conduct a cumulative risk assessment laid a broad foundation for continued development of cumulative risk approaches. The 2003 Framework describes some basic considerations for conducting a cumulative risk assessment and outlines four areas of population vulnerability: Susceptibility or sensitivity, differential exposure (e.g., living in close proximity to pollutant sources), differential preparedness (e.g., lack of disease immunizations), and differential ability to recover from exposures. Since 1986, U.S. EPA technical and guidance documents have been published that address chemical mixture risk assessments which can be used for cumulative risk assessment, but additional research has been needed to address chemical mixtures in combination with multiple exposures and effects.

In February 2001, the U.S. EPA began collaborating with the U.S. DOE in an effort to collect data and develop methods for use in cumulative risk assessments. This present document, ''Concepts, Methods, and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures, and Effects: A Resource Document,'' is the final product of that effort. It further develops the knowledge base for conducting cumulative risk assessments by providing details regarding the evaluation of the human health and population aspects of cumulative risk assessment and by introducing practical ideas for addressing multiple chemicals, exposures, and effects.

The U.S. EPA released the external review draft in March 2006 for a 45-day public comment period (see 71 FR 16306–16307, March 31, 2006; Docket ID No. EPA–HQ–ORD–2006–0223). The draft received an independent peer review conducted by the Eastern Research Group under U.S. EPA contract number 68–C–02–060. The peer review included a two-day workshop in May 2006 and featured an external panel of scientific reviewers (see 71 FR 26365–26366, May 4, 2006; Docket ID No. EPA–HQ–ORD–2006–0223).

Dated: June 20, 2008.

Rebecca Clark,

Acting Director, National Center for Environmental Assessment.

[FR Doc. E8–14623 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8686–4]

Conference Call of the Total Coliform Rule Distribution System Advisory Committee—Notice of Public Conference Call

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Under Section 10(a)(2) of the Federal Advisory Committee Act, the United States Environmental Protection Agency (EPA) is giving notice of a conference call of the Total Coliform Rule Distribution System Advisory Committee (TCRDSAC). The purpose of this conference call is to discuss the Total Coliform Rule (TCR) revisions and information about distribution systems issues that may impact water quality.

The TCRDSAC advises and makes recommendations to the Agency on revisions to the TCR, and on what information should be collected, research conducted, and/or risk management strategies evaluated to better inform distribution system contaminant occurrence and associated public health risks.

Topics to be discussed during the conference call include options for revising the Total Coliform Rule; for example, rule construct, monitoring provisions, system categories, action levels, investigation and follow-up, public notification, and other related topics. In addition, the Committee will discuss possible recommendations for research and information collection needs concerning distribution systems and topics for upcoming TCRDSAC meetings.

DATES: The public conference call will be held on Friday, July 18, 2008 (1 p.m. to 4 p.m., Eastern Time (ET)). To register for the conference call and receive the call in information, attendees should contact Kate Zimmer at (202) 965–6387 or by e-mail to *kzimmer@resolv.org* no later than July 15, 2008.

FOR FURTHER INFORMATION CONTACT: For general information, contact Kate Zimmer of RESOLVE at (202) 965–6387. For technical inquiries, contact Sean Conley (*conley.sean@epa.gov*, (202) 564–1781), Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC 4607M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; fax number: (202) 564–3767.

SUPPLEMENTARY INFORMATION: The conference call is open to the public. The Committee encourages the public's input and will take public comment starting at 2:15 p.m. on July 18, 2008, for this purpose. It is preferred that only one person present the statement on behalf of a group or organization. To ensure adequate time for public involvement, individuals interested in presenting an oral statement may notify Crystal Rodgers-Jenkins, the Designated Federal Officer, by telephone at (202) 564–5275, no later than July 15, 2008. Any person who wishes to file a written statement can do so before or after a Committee meeting or conference call. Written statements received by July 15, 2008, will be distributed to all members before any final discussion or vote is completed. Any statements received on July 16, 2008, or after the conference call, will become part of the permanent meeting and conference call file and will be forwarded to the members for their information.

Special Accommodations

For information on access or accommodations for individuals with disabilities, please contact Crystal Rodgers-Jenkins at (202) 564–5275 or by e-mail at *rodgers-jenkins.crystal@epa.gov.* Please allow at least 10 days prior to the conference call to give EPA time to process your request.

Dated: June 24, 2008.

Cynthia Dougherty,

Director, Office of Ground Water and Drinking Water.

[FR Doc. E8–14620 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2008–0459; FRL–8370–5]

Electronic Submission of Certain Pesticide Applications and Data; Availability of Guidance Website

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

SUMMARY: As of July 15, 2008, the Office of Pesticide Programs (OPP) will begin accepting certain types of pesticide applications and associated data electronically. The types of applications that will be accepted electronically are Section 3 applications and amendments, Experimental Use Permits, Tolerance Petitions, and Supplemental Distributor Applications. To assist pesticide registrants to properly format their electronic submissions, OPP has established a new web site. This Notice announces the availability of that web site. This site can be accessed at *http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm.*

FOR FURTHER INFORMATION CONTACT: John Jamula, Information Technology and Resources Management Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305-6426; fax number: (703) 305-7670; e-mail address: *jamula.john@epa.gov.* Or you may contact the E-submission help desk Toll Free: 1-866-612-8664. Voice-mail can be left at any time. E-mail Address: *OPPeSubmissionHelpdesk@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you produce pesticides. Potentially affected entities may include, but are not limited to: Pesticide Registrants.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0459. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr.*

II. Background

What Action is the Agency Taking?

As of July 15, the Office of Pesticide Programs (OPP) will begin accepting certain types of pesticide applications and associated data electronically. The types of applications that will be accepted electronically are Section 3 applications and amendments, Experimental Use Permits, Tolerance Petitions, and Supplemental Distributor

Applications. To assist pesticide registrants to properly format their electronic submissions, OPP has established a new web site. This notice announces the establishment of a new Internet website that contains guidance that will be useful to pesticide companies planning to submit pesticide applications and data electronically. This site can be accessed at *http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm*.

List of Subjects

Dated: June 16, 2008.

Oscar Morales

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. E8–14612 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8583–2]

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 FR dated April 11, 2008 (73 FR 19833).

Draft EISs

EIS No. 20080134, ERP No. D–NPS–F65070–MI, Sleeping Bear Dunes National Lakeshore, General Management Plan and Wilderness Study, Implementation, Benzie and Leelanau Counties, MI.

Summary: EPA does not object to the proposed action. Rating LO.

EIS No. 20080083, ERP No. DS–AFS–D65039–WV, Lower Williams Project Area (LWPA), Additional Information, Proposed to Perform Vegetation Management and Wildlife Habitat Improvements, Implementation, Gauley Ranger District, Monongahela National Forest, Webster County, WV.

Summary: EPA expressed environmental concerns about potential adverse impacts to both aquatic and terrestrial habitat. The final EIS should include mitigation measures to minimize impacts to streams and aquatic habitat resources. Rating EC2.

Final EISs

EIS No. 20080177, ERP No. F–USN–K11119–HI, Hawaii Range Complex (HRC) Project, Preferred Alternative is 3, To Support and Maintain Navy Pacific Fleet Training, and Research, Development, Test, and Evaluation (RDT&E) Operations, Kauai, Honolulu, Maui and Hawaii Counties, HI.

Summary: EPA expressed environmental concerns about impacts to marine resources from mid-frequency active (MFA) sonar use and the deposition of hazardous materials into water resources from munitions and training expenditures.

EIS No. 20080182, ERP No. F–AFS–G65106–NM, Perk-Grindstone Fuel Reduction Project, to Protect Life, Property, and Natural Resources, Village of Ruidoso, Lincoln National Forest, Lincoln County, New Mexico.

Summary: No formal comment letter was sent to the preparing agency.

EIS No. 20080201, ERP No. F–AFS–J65511–SD, Upper Spring Creek Project, Proposes to Implementation Multiple Resource Management Actions, Mystic Ranger District, Black Hills National Forest, Pennington and Custer Counties, SD.

Summary: No formal comment letter was sent to the preparing agency.

Dated: June 24, 2008.

Ken Mittelholtz,

Environmental Protection Specialist, Office of Federal Activities.

[FR Doc. E8–14624 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–8583–1]

Environmental Impacts 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 June 16, 2008 Through June 20, 2008

Pursuant to 40 CFR 1506.9.

EIS No. 20080241, Draft EIS, USN, 00, Virginia Capes (VACAPES) Range Complex, Proposed action is to Support and Conduct Current and Emerging Training and RDT & E Operations, Chesapeake Bay, DE, MD, VA and NC, *Comment Period Ends:* 08/11/2008, *Contact:* Karen Foskey 703–602–2859.

EIS No. 20080242, Draft EIS, BLM, VA, East Lynn Lake Coal Lease Project, Proposal to Lease Federal Coal that lies under Nine Tracts of Land for Mining, Wayne County, VA, *Comment Period Ends:* 09/24/2008, *Contact:* Chris Carusona 414–297–4463.

EIS No. 20080243, Draft EIS, USN, 00, Jacksonville Range Complex Project, To Support and Conduct Current and Emerging Training and RDT&E Operations, NC, SC, GA and FL, *Comment Period Ends:* 08/11/2008, *Contact:* Karen Foskey 703–602–2859.

EIS No. 20080244, Final EIS, FAA, FL, Fort Lauderdale-Hollywood International Airport, Proposed Development and Extension of Runway 9R/27L and other Associated Airport Projects, Funding, U.S. Army COE Section 404 Permit and NPDES Permit, Fort Lauderdale, Broward County, FL, *Wait Period Ends:* 07/28/2008, *Contact:* Virginia Lane 407–812–6331.

EIS No. 20080245, Final EIS, FHW, UT, I–15 Corridor Project, Transportation Improvement from Utah County to Salt Lake County, UT, *Wait Period Ends:* 07/28/2008, *Contact:* Carlos C. Machado 801–963–0182.

EIS No. 20080246, Final Supplement, AFS, UT, West Bear Vegetation Management Project, Additional Information to Improve a Portion of the Cumulative Effects Analysis and Correct the Soils Analysis, Timber Harvesting, Prescribed Burning, Roads Construction, Township 1 North, Range 9 East, Salt Lake Principle Meridian, Evanston Ranger District, Wasatch-Cache National Forest, Summit County, UT, *Wait Period Ends:* 07/28/2008, *Contact:* Larry Johnson 307–783–3790.

EIS No. 20080247, Final EIS, NCP, DC, Smithsonian Institution National Museum of African American History and Culture, Construction and Operation, Between 14th and 15th Streets, NW., and Constitution Avenue, NW., and Madison Drive, NW., Washington, DC, *Wait Period Ends:* 07/28/2008, *Contact:* Gene Keller 202–482–7251.

EIS No. 20080248, Final EIS, AFS, ID, Idaho Cobalt Project, Development of Two Underground Mines, a Waste Disposal Site and Associated Facilities, Approval of Plan-of-Operation, Salmon-Cobalt Ranger District, Salmon-Challis National Forest, Lemhi County, ID, *Wait Period Ends:* 07/28/2008, *Contact:* Kimberly Nelson 208–756–5200.

EIS No. 20080249, Final Supplement, BLM, WY, Pinedale Anticline Oil and Gas Exploration and Development Project, Additional Information on Two New Alternatives, Consolidated Development with Year-Round Development (Construction, Drilling, Completion, and Production), Sublette County, WY, *Wait Period Ends:* 07/28/2008, *Contact:* Caleb Hiner 307–367–5352.

EIS No. 20080250, Draft EIS, FHW, CA, Orange County Gateway Project, To Provide Grade Separation Alternative along the Burlington Northern Santa Fe Railroad Tracks from west of Bradford Avenue to west of Imperial Highway (State Route 90), Cities of Placentia and Anaheim, Orange County, CA, *Comment Period Ends:* 08/11/2008, *Contact:* Scott McHenry 916–498–5854.

EIS No. 20080251, Draft EIS, AFS, CA, Moonlight and Wheeler Fires Recovery and Restoration Project, Proposes to Harvest Fire-Killed Merchantable Trees on 15,568 Acres, Mt. Hough Ranger District, Plumas National Forest, Plumas County, CA, *Comment Period Ends:* 08/11/2008, *Contact:* Rich Bednarski 530–283–7641.

EIS No. 20080252, Draft EIS, DHS, 00, National Bio and Agro-Defense Facility, Proposal to Site, Construct, and Operate at one of the Proposed Locations: (1) South Milledge Avenue Site, Clarke County, GA; (2) Manhattan Campus Site, Riley County, KS; (3) Flora Industrial Park Site, Madison County, MS; (4) Plum Island Site, Suffolk County, NY; (5) Umstead Research Park Site, Granville County, NC; and (6) Texas Research Park Site, Bexar and Medina Counties, TX, *Comment Period Ends:* 08/25/2008, *Contact:* James V. Johnson 202–254–6098.

EIS No. 20080253, Draft EIS, NOA, 00, Amendment 4 to the Spiny Lobster Fishery Management Plan of Puerto Rico and the U.S. Virgin Islands and Amendment 8 to the Spiny Lobster Fishery Management Plan of the Gulf of Mexico and South Atlantic, To Address the Harvest and Exportation of Undersized Lobster Tails to the United States, *Comment Period Ends:* 08/11/2008, *Contact:* Roy E. Crabtree, PhD 727–824–5301.

EIS No. 20080254, Final EIS, NOA, MA, ADOPTION—Neptune Liquefied Natural Gas (LNG), Construction and Operation, Deepwater Port License Application, (Docket Number USCG–2004–22611) Massachusetts Bay, Gloucester and Boston, MA, *Contact:* James H. Lecky 301–713–2332. US DOC/NOA adopted the US CGD & MARAD Final Supplemental EIS 20060451 filed 10/27/2006. NOA was a cooperating agency on the project. Recirculation of the document is not necessary under 1506.3(b) of the CEQ Regulations.

Amended Notices

EIS No. 20080200, Draft EIS, AFS, UT, Dixie National Forest Motorized Travel Plan, Implementation, Dixie National and the Teasdale portion of the Fremont River Ranger District on the Fishlake National Forest, Garfield, Iron, Kane, Piute, Washington and Wayne Counties, UT, *Comment Period Ends:* 07/22/2008, *Contact:* Andi Falsetto 435–896–9233. Revision of FR Notice Published 05/23/2008: Extending Comment Period 07/07/2008 to 07/22/2008.

Dated: June 24, 2008.

Ken Mittelholtz,

Environmental Protection Specialist, Office of Federal Activities.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2008–0267; FRL–8371–5]

Formaldehyde Emissions from Composite Wood Products; Disposition of TSCA Section 21 Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On March 24, 2008, 25 organizations and approximately 5,000 individuals petitioned EPA under section 21 of the Toxic Substances Control Act (TSCA) to use section 6 of TSCA to adopt a recently promulgated California State regulation concerning emissions of formaldehyde from three types of composite wood products: Hardwood plywood, particleboard, and medium density fiberboard. They petitioned EPA to assess and reduce the risks posed by formaldehyde emitted from these products by exercising its authority under TSCA section 6 to: Adopt and apply nationally the California formaldehyde emissions regulation for these composite wood products; and to extend the regulation to include composite wood products used in manufactured homes. For the reasons set forth in this notice, EPA has granted in part and denied in part the petitioners' requests.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Linter, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Mary Belefski, Chemical Control Division (7405M), Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8461; e-mail address: *belefski.mary@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who manufacture, process, import, or distribute in commerce composite wood products, including hardwood plywood, particleboard, or medium density fiberboard and others who are interested in Agency activities involving formaldehyde. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Information About This Petition?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2008–0267. All documents in the docket are listed in the docket's index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is

(202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

II. Background

A. What is a TSCA Section 21 Petition?

Section 21 of TSCA allows any person to petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or the expiration of the 90–day period.

B. What Criteria Apply to a Decision on a TSCA Section 21 Petition?

1. *Legal standards regarding TSCA section 21 petitions.* Section 21(b)(1) of TSCA requires that the petition ''set forth the facts which it is claimed establish that it is necessary'' to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B). Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested to evaluate this petition.

2. *Legal standard regarding TSCA section 6 rules.* In order to promulgate a rule under TSCA section 6(a), the Administrator must find that ''there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk.'' 15 U.S.C. 2605(a). This finding cannot be made considering risk alone. In promulgating any rule under TSCA section 6(a), the statute requires that the Administrator consider:

- The effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture.
- The effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture.
- The benefits of such substance or mixture for various uses and the availability of substitutes for such uses.
- The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health. 15 U.S.C. 2605(c)(1).

Furthermore, the control measure or measures adopted are to be the ''least burdensome requirements'' that adequately protect against the unreasonable risk. 15 U.S.C. 2605(a).

Section 21(b)(4)(B) of TSCA provides the standard for judicial review should EPA deny a request for rulemaking under TSCA section 6(a): ''If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that ... there is a reasonable basis to conclude that the issuance of such a rule ... is necessary to protect health or the environment against an unreasonable risk of injury,'' the court shall order the Administrator to initiate the requested action. 15 U.S.C. 2620(b)(4)(B).

C. What Action is Requested Under this TSCA Section 21 Petition?

On March 24, 2008, the Sierra Club, National Center for Healthy Housing, National Coalition to End Childhood Lead Poisoning, Alliance for Healthy Homes, National Housing Institute, Healthy Building Network, Gulf Coast Environmental Restoration Task Force of Sierra Club, Next Generation Choices Foundation, Improving Kids' Environment, EarthRose Institute, Grassroots Environmental Education, Healthy Homes of Louisiana, Lower Mississippi Riverkeeper, Women's Community Cancer Project, Gulf Coast D'Iberville Volunteers Foundation, Advocates for Environmental Human Rights, Environmental Health Watch, North Gulfport Community Land Trust, Louisiana Environmental Action Network, Allergy and Environmental Health Assoc., Aspen River Construction, DeVany Industrial Consultant, Protect Sacred Sites ''Indigenous People, One Nation,'' United People of the Cherokee Nation, Clean Air Athens, and approximately 5,000 individuals petitioned EPA under TSCA section 21. The petitioners are concerned about risks to human health from exposure to formaldehyde emitted from composite wood products, including hardwood plywood, particleboard, and medium density fiberboard. They petitioned EPA to assess and reduce these risks by exercising its authority under TSCA section 6 to:

1. Adopt and apply nationally the formaldehyde emissions regulation (Airborne Toxics Control Measure (ATCM)) for three types of composite wood products (hardwood plywood, particleboard, and medium density fiberboard), recently adopted by the California Air Resources Board (CARB).
2. Extend the regulation to include composite wood products used in manufactured housing.

Among other requirements, the CARB ATCM specifies cap emission limits that are not to be exceeded.

In this notice, unless otherwise specified, ''composite wood products'' refers to the three types of wood products (hardwood plywood, particleboard, and medium density fiberboard) referred to in the California regulation. Composite wood products are a subset of ''pressed wood products.''

D. What Support Do the Petitioners Offer for These Requests?

To support their request, the petitioners referenced CARB's webpage containing the documentation supporting the composite wood products rulemaking. In addition, petitioners cited information available from Federal agencies including the following:

1. U.S. Department of Housing and Urban Development (HUD), Office of Manufactured Housing Programs, and HUD's formaldehyde emission control regulations at 24 CFR 3280.308.
2. The U.S. EPA National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products at 40 CFR part 63, subpart DDDD regulation.
3. The U.S Occupational Safety and Health Administration, Formaldehyde Standards for Toxic and Hazardous Substances, 29 CFR 1910.1048.
4. The U. S. Centers for Disease Control and Prevention (CDC) analyses and findings on formaldehyde in the Federal Emergency Management Agency's (FEMA) Hurricane Katrina trailers. The petitioners also

summarized in their submission the findings on exposure levels from the CDC trailer study.

III. Comments Received

In response to EPA's request for comment on this TSCA section 21 petition (73 FR 22369, April 25, 2008) (FRL–8362–6), EPA received 25 comments. Three were short comments in support of the petition from concerned citizens and furniture manufacturers; one additional furniture manufacturer commented on his concern about effective enforcement against furniture importers. Another comment cautioned that developing a compliance testing method may be very difficult.

Eight manufactured housing trade groups and suppliers submitted similar comments opposed to EPA regulation of manufactured homes. The commenters stated that the HUD's standards have not been shown to be inadequate, HUD has the appropriate statutory authority (and EPA should use TSCA section 9 to refer the matter to HUD), and HUD has already received recommendations to amend its standards. Five furniture, window, door, and general manufacturing trade groups indicated their support for national application of formaldehyde emission standards, but noted that several challenges to the implementation and enforcement of California's rule still need to be worked out. Some indicated support for EPA development of a ''performance-based standard'' designed to reduce human exposure to formaldehyde, regardless of source (mentioning carpet and paints as other sources of formaldehyde exposure) and all were concerned about the administrative burdens of the CARB rule and California's or EPA's ability to manage the certification and testing requirements.

Three plywood and composite panel trade groups indicated support for expanding CARB's emission limits to the rest of the United States, but commented that a TSCA section 6 rule is neither appropriate nor justifiable. They suggest that a national standard would be ''developed in a cooperative effort with industry'' rather than through a TSCA section 6 rule. The Hardwood Plywood & Veneer Association (HPVA) stated that it would be willing to join the Manufactured Housing Institute to petition HUD to adopt the CARB standards, and is considering incorporating the CARB emission standards into their next revision of the American National Standards Institute-HPVA standards for hardwood plywood and engineered hardwood flooring. The American Forest & Paper Association commented that it ''supports adoption by EPA of the ATCM emission standards and testing and labeling provisions as a single, national paradigm for formaldehyde in composite wood panels, but developed in a cooperative effort with industry rather than through an (unjustified) Section 6 rule.'' The Composite Panel Association (CPA) estimated that 80% of their members' medium density fiberboard and particleboard production will be CARB-compliant, and CPA expects the CARB rule to become a de facto national standard. However, since compliance with the Phase 2 standards will be significantly more expensive, CPA commented that there will be a greater incentive to differentiate panel emission level by region or customer. CPA also noted that the industry estimates that the costs of the CARB rule, nationwide, will be close to $650 million, significantly higher than the cost to affected parties predicted by California (commenters stated that CARB's cost estimate was $147 million, but it is actually $127 million). HPVA and CPA also noted concerns about the ability of California or the EPA to enforce the regulation against importers of panels and finished products, and suggested that imports may be a main source of higher emitting panels and finished products.

Comments were also received from a formaldehyde trade group and from a resin manufacturer. Hexion, a ''major global supplier of thermosetting adhesives,'' opposed EPA using section 6 to adopt the California rule, but ''could support a national, preemptive regulation limiting formaldehyde emissions from composite wood products . . .'' The Formaldehyde Council, Inc. (FCI) disagreed with the idea that there is no safe level of exposure to formaldehyde. FCI also commented that the average level detected in the FEMA trailers does not typically cause sensory irritation, and cited a study of conventional homes, finding an average formaldehyde concentration of 0.37 parts per million (ppm) (370 parts per billion (ppb)), in which the occupants had not complained of irritation. They also cited studies that show sensory irritation thresholds of 0.5 ppm (500 ppb), and up to 0.9 ppm (900 ppb) for unsensitized people, and asserted that the empirical support for the studies that the International Agency for Research on Cancer (IARC) relied on to recategorize formaldehyde has been ''steadily eroded.''

The Sierra Club commented on the TSCA section 6(c) factors and suggested that EPA consider cost factors associated with remediating the problems in the FEMA trailers. They suggested that EPA estimate the effect on the national economy by a simple mathematic extrapolation from the costs estimated by California and argue that adopting the ATCM would spur technological innovation and have a positive impact on human health and the environment.

HUD commented that it received (prior to EPA's receipt of this petition) a proposal to lower formaldehyde emissions limits from certain products used in the construction of manufactured homes from the Congressionally established Federal Advisory Committee, the Manufactured Housing Consensus Committee (MHCC). In addition, the MHCC recently received a new proposal from the public to adopt the CARB standard. HUD commented that it will work with the MHCC to review the new proposal regarding CARB levels. A supplemental comment was received from HUD on June 19, 2008, and is in the docket.

On June 13, 2008, EPA received an additional comment from CPA, summarizing new developments since they submitted their first comment. As also noted in their first comment, CPA is accredited by the American National Standards Institute (ANSI) as a standards developer. On June 3, 2008, the CPA Board of Directors ''approved the insertion of the CARB Phase 1 and Phase 2 formaldehyde emission limits'' into the new versions of the ANSI standards for Particleboard (ANSI A208.1) and for Medium Density Fiberboard (ANSI A208.2). When the standards are finalized, ''companies would be able to reference either of those levels from these voluntary standards in their commercial dealings.'' A consensus committee must still approve the revised standard. A supplemental comment was also received from HPVA on June 17, 2008, and is in the docket.

IV. Disposition of Petition

For the purpose of making its decision, EPA evaluated the information presented or referenced in the petition and its authority and requirements under TSCA sections 6 and 21. EPA also evaluated comments submitted and relevant information that was otherwise available to EPA during the 90–day petition review period. On the basis of the significant differences in the legal standards applicable to the California Health and Safety Code (H&SC) and TSCA section 6, and the insufficiency of the information available to EPA for purposes of conducting the TSCA section 6 analysis, EPA is not granting

the specific request in the petition to commence a proceeding under TSCA section 6 to impose the CARB formaldehyde ATCM nationwide. Even if the information available to EPA were sufficient to support an evaluation of whether formaldehyde in composite wood products presents or will present an unreasonable risk, petitioners have not provided sufficient information, and EPA does not otherwise have sufficient information, to evaluate whether the CARB ATCM would likely be the least burdensome alternative necessary to protect adequately against such risk. However, EPA has decided to initiate a proceeding to investigate whether and what type of regulatory or other action might be appropriate to protect against risks posed by formaldehyde emitted from pressed wood products.

The discussion that follows provides the reasons for EPA's decisions to grant this petition in part and to deny it in part.

A. EPA is Not Granting the Petitioners' Specific Requests

1. *Differences between California's authority under State law, and EPA's authority under TSCA*. The petition requests that EPA use authorities under section 6 of TSCA to ''adopt the California rules and apply them nationally,'' and apply them to composite wood products used in manufactured housing (Ref. 1). The authority under which the State of California issued its ATCM is quite distinct from the regulatory authority granted to EPA under TSCA, however, and EPA has determined that its authority under section 6 of TSCA does not permit it to simply adopt the California formaldehyde ATCM and impose these regulatory controls as a Federal standard without independently determining that formaldehyde in the relevant materials presents or will present an ''unreasonable risk'' under TSCA section 6(a). Neither the CARB rulemaking record nor other information available to EPA is adequate to support an evaluation of whether the use of formaldehyde in composite wood products presents or will present an unreasonable risk.

CARB's authority to regulate formaldehyde is discussed on pages 2–3 of CARB's ''Initial Statement of Reasons'' (ISOR), which was used to support its rulemaking (Ref. 2). According to the statement of authority in the ISOR, CARB asserted jurisdiction to regulate formaldehyde in composite wood products under the California H&SC. The H&SC authorizes CARB to control emissions of criteria pollutants and precursors from source categories. In addition, CARB is authorized to regulate toxic air contaminants (TACs) under that portion of the H&SC known as the Tanner Act. In 1992, CARB identified formaldehyde as a TAC ''based primarily on the determination that it was a human carcinogen with no known safe level of exposure'' (Ref. 2). According to the ISOR, CARB's formaldehyde ATCM was issued principally under the Tanner Act on the basis of formaldehyde being a TAC. Because CARB had identified formaldehyde as a TAC ''with no identified 'safe' threshold exposure level,'' it was required by the Tanner Act ''to reduce emissions of the TAC to the lowest level achievable through application of BACT (best available control technology) or a more effective control method.''

The TSCA section 6 authority specifically requested by the petition to be used to adopt and apply nationally the CARB ATCM is significantly different from CARB's authority under the H&SC. As discussed in Unit II.B.2., under TSCA section 6(a), EPA must make a finding that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical presents or will present an unreasonable risk of injury to health or the environment in order to promulgate a TSCA section 6(a) rule. The CARB rulemaking record does not analyze the issues in these terms because CARB does not have to make an unreasonable risk finding under the California H&SC.

TSCA section 6(a) identifies the actions that may be taken to protect against unreasonable risk, but does not prescribe a particular minimum control measure as California's law prescribes BACT. If EPA finds that there is a reasonable basis to conclude that one or more activities presents an unreasonable risk, EPA may:

- Prohibit or limit manufacture, processing, or distribution in commerce;
- Prohibit or limit the manufacture, processing, or distribution in commerce of the chemical above a specified concentration;
- Require adequate warnings and instructions with respect to use, distribution, or disposal;
- Require recordkeeping;
- Prohibit or regulate any manner of commercial use;
- Prohibit or regulate any manner of disposal; or
- Require manufacturers or processors to give notice of the unreasonable risk of injury.

TSCA section 6(a) also states that EPA must determine which one or more of the risk management options set forth in the statute are the least burdensome means of adequately protecting against the risk. The CARB rulemaking record was constructed to support the single option (BACT or more effective control method) available under the California H&SC, and not for choosing from the multiple options available under TSCA. The California H&SC also does not require that CARB choose the least burdensome means of protecting adequately against the risk.

2. *Information in the petition and otherwise available to EPA is inadequate to support an unreasonable risk evaluation under TSCA*. Notwithstanding the substantial amount of information submitted by reference with the petition or otherwise available to the Agency, EPA has determined that this information is not sufficient to support an evaluation of whether formaldehyde emitted from composite wood products presents or will present an unreasonable risk to human health (including cancer and non-cancer endpoints) under TSCA section 6. Applying the TSCA section 6(a) and 6(c) requirements to the information provided by the petitioners reveals significant information gaps that would need to be filled to support an evaluation of whether use of formaldehyde in composite wood products presents or will present an unreasonable risk. EPA briefly summarizes its reasoning in this unit.

a. *Health risks and exposure*. With respect to health risks, the petition refers to the CARB record and to the CDC study on FEMA trailers, thus looking at both cancer risk and irritation risk. CARB based their health effects evaluation on cancer risk. In 1992, CARB identified formaldehyde as a TAC ''based primarily on the determination that it was a human carcinogen with no known safe level of exposure'' (Ref. 2). CARB also cites for support the higher (hazard) classification of formaldehyde as ''Group 1, Carcinogenic to humans'' by the International Agency for Research on Cancer (IARC) (Ref. 2, p. 155, see also Ref. 3). CARB's analysis was dependent on its determination of formaldehyde as a human carcinogen and its assumptions and analyses that rely on animal data and use two different kinds of models, the linearized multi-stage model and a model which takes into account the proliferation of premalignant cells, for quantification of the cancer risk. In this analysis CARB relied upon the animal data considered by EPA in its 1991 analysis and applied an additional model which places the result somewhere between that of EPA's 1991 assessment and that of the Chemical Industry Institute of

Toxicology's (CIIT) biologically based dose response (BBDR) approach used in EPA in 2004 (discussed in this unit). Given the recent availability of human cancer data which may provide the basis of a more appropriate quantification of human cancer risk, EPA questions the adequacy of the CARB approach and for this reason as well as other reasons discussed in this unit, EPA has determined that it is not able to rely on CARB's cancer risk assessment.

EPA has previously assessed formaldehyde's cancer risk. In 1991, EPA classified formaldehyde as a B1, probable human carcinogen, ''based on limited evidence in humans, and sufficient evidence in animals'' (Ref. 4). Increased incidences of nasal squamous cell carcinomas were observed in long-term inhalation studies in rats and mice. Based on the nasal cavity cancer data in rats and using a linearized multi-stage procedure (for genotoxic effects), EPA calculated an inhalation cancer unit risk/potency factor of 1.3 E-5 per microgram/meter cubed ($\mu g/m^3$) (Ref. 4). As explained in this unit, the assessment and modeling procedure used to develop EPA's cancer risk assessment is not based on the most current information, and EPA may determine that the appropriate unit risk/potency factor is higher or lower than the 1991 value, after considering the currently available scientific information, including human data.

CIIT developed a health risk assessment for formaldehyde based upon animal toxicology data that utilized mechanistic and biological response information to develop a dose response model for the risk of squamous cell carcinoma in the respiratory tract (Ref. 5). The resulting BBDR model was published in the peer reviewed literature (Refs. 6–8). The cancer estimates obtained with the BBDR model are generally 2–3 orders of magnitude lower than corresponding estimates obtained with the linearized multistage procedure. In 2004, EPA's Office of Air and Radiation (OAR) determined that the CIIT's BBDR model was the most appropriate tool to assess the potential cancer risk associated with formaldehyde emissions to the atmosphere (Refs. 9–11). In the Plywood and Composite Wood Products National Emission Standard for Hazardous Air Pollutants (NESHAP), which was issued in 2006, OAR stated ''In the case of formaldehyde, we have determined that the cancer potency derived using the approach developed by CIIT, which has been peer reviewed by an external review panel sponsored by EPA and the Canadian government, represents an appropriate alternative to EPA's current IRIS URE for formaldehyde. Therefore, this potency represents the best available peer-reviewed science at this time.'' (Ref. 10, p. 8348).

In April 2008, the EPA Office of Pesticide Programs (OPP) issued a preliminary risk assessment of formaldehyde for the reregistration eligibility decision (RED) as part of Phase 3 of a modified, 4-Phase public participation process that the Agency uses to involve the public in developing pesticide reregistration decisions (Ref. 12). Through the reregistration program, EPA is ensuring that all pesticides meet current health and safety standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). In this preliminary risk assessment, OPP decided to present the formaldehyde cancer risks as a range using both the 1991 EPA assessment and the CIIT BBDR model (Ref. 15). This approach, which recently underwent public comment, brackets a range of cancer risk estimates that span about three orders of magnitude (or a factor of a thousand), and depending on which value is being considered suggests potentially significant risk at one end and potentially insignificant risk at the other. In addition to these assessments, IARC, in their reevaluation of epidemiologic studies, concluded that there was ''sufficient epidemiological evidence that formaldehyde causes nasopharyngeal cancer in humans,'' and upgraded formaldehyde to ''Group 1, carcinogenic to humans'' from ''Group 2A, probably carcinogenic to humans'' (Ref. 3). In addition, IARC concluded that ''there is strong but not sufficient evidence for a causal association between leukemia and occupational exposure to formaldehyde'' (Ref. 3). With these new human data, and considering the other available data, EPA's Office of Research and Development (ORD) is currently engaged in a re-assessment/update of the potential cancer and non-cancer risks of formaldehyde through the ORD Integrated Risk Information System (IRIS) program. An external peer review draft of this assessment is expected to be released in 2009. EPA offices which may be considering or are actively regulating formaldehyde, including the Office of Pollution Prevention and Toxic Substances (OPPTS), will coordinate and proceed accordingly once the assessment is finalized.

As discussed previously, because of the uncertainties in estimating formaldehyde's cancer risks, and the ongoing development of the science with respect to cancer characterization and risk estimation based on the new human data, EPA has determined that it cannot rely on the CARB cancer assessment and believes it would be premature to render judgment on this complex issue for TSCA section 6 purposes. Thus, EPA does not believe that it has information sufficient to support an evaluation of whether formaldehyde in composite wood products presents or will present an unreasonable risk.

In addition, in the chronic exposure analysis for composite wood, the CARB rulemaking record makes assumptions that are not believed to be reasonable for use in an EPA risk assessment. For example, CARB assumed that individuals will live in new houses (and have associated elevated formaldehyde exposures) for 70 years. Their analysis did not account for formaldehyde concentration decay over time in new home environments, and they assumed all time spent indoors is spent at the same average formaldehyde concentration as at home, and that all time at home is spent indoors (Ref. 13).

With respect to irritation risk, the CDC study on FEMA trailers cited by petitioners provides data on exposure to formaldehyde in trailers, but does not provide a risk analysis. CARB did not rely on irritation risks for their decision to regulate formaldehyde emissions from composite wood products.

For these reasons, EPA believes that the information available on health risks (including cancer and non-cancer effects) and exposure is not adequate to support an unreasonable risk evaluation.

b. *Economics*. The economic analysis supporting CARB's ATCM is inadequate to support an evaluation of whether formaldehyde in composite wood products presents or will present an unreasonable risk. In its ISOR, CARB quantified some of the costs and benefits for the ATCM, but not all of the costs or any non-cancer benefits.

The ISOR estimated, for example, the cost for industry to comply with the ATCM using various substitute resin systems and discussed the characteristics, advantages, and disadvantages of these substitutes, as well as their effectiveness in reducing formaldehyde emissions from composite wood products. The ISOR cost estimate was based on the cost to purchase substitute resins and on the longer processing times required to manufacture composite wood products when using certain substitute resins. CARB received public comments on its rulemaking that companies will incur additional costs to manufacture

compliant panels due to increased costs for resin additives, new equipment, additional energy usage, or decreased throughput. In responding to these comments, CARB indicated that these costs would not necessarily be incurred, and that it expected future innovations in resin technology would decrease production costs over time. EPA suspects that the CARB analysis underestimated costs, particularly in the short term. But EPA was not able to assess the full extent of the likely costs based on the information available. For example, the ISOR cost estimate also does not fully reflect other requirements of the ATCM, such as third party certification and labeling. In addition, because data were not available on the quantity of composite wood contained in imported fabricated goods such as cabinets and furniture, the ISOR cost estimates did not reflect the increase in the cost of these goods. Thus, the information submitted provides an inadequate basis for assessing total incremental cost for the ATCM, or for a national version of the ATCM, including certification, labeling, and related activities required by the ATCM.

The trade associations representing composite wood product manufacturers have indicated that the CARB limits may have a significant impact on the national markets. For example, CPA estimated that 80% or more of its members' production nationwide will be compliant with CARB's requirements. The associations indicated, however, that they could not estimate how foreign manufacturers and importers will respond to the ATCM and that off-shore producers are an issue because they do not participate in the same voluntary compliance programs that are applicable to domestic producers. Furthermore, especially in view of the expected growth in imports of composite wood products and the fabricated goods made from them, the national baseline following the implementation of the CARB rule, which EPA would use as a starting basis in assessing whether there is an unreasonable risk, is uncertain (Ref. 13).

In addition to cancer benefits, the ATCM may result in benefits from avoided cases of non-cancer effects. The CARB ISOR does not, however, present sufficient information to assess benefits from non-cancer effects. For example, the CARB ISOR mentions a hazard quotient for non-cancer inhalation impacts, but the hazard quotient was not evaluated to estimate the number of people exposed to a hazard quotient above 1, the aggregate length of time that such exposures occur, and the intensity of the exposure over time. In addition, the ISOR did not provide information on the size of the population exposed or the intensity of exposure from composite wood products in remodeled homes, newly purchased furniture, or non-residential settings. The benefits of avoiding irritation effects include reductions in medical costs, individuals' willingness to pay to avoid the pain and suffering resulting from these effects, and increases in productivity due to a decline in lost work days and school days. The ISOR and the other information available to EPA does not provide sufficient information to estimate the non-cancer benefits.

Thus, EPA does not have sufficient information to support an evaluation of the costs and benefits of implementing the ATCM requirements nationwide.

3. *Information in the petition and otherwise available to EPA is insufficient to support an evaluation of whether the CARB rule would be the least burdensome requirement under TSCA.* Even if the information available to EPA were sufficient to support an evaluation of whether formaldehyde in composite wood products presents or will present an unreasonable risk, petitioners have not provided sufficient information, and EPA does not otherwise have sufficient information, to evaluate whether the CARB ATCM would likely be the least burdensome alternative necessary to protect adequately against such risk. The information submitted with the petition does not provide an adequate basis for EPA to evaluate the likely costs and benefits of less burdensome alternatives. This is not surprising, since the CARB rulemaking does not require such an analysis. For example, EPA has no basis to evaluate whether the specific emission levels adopted by CARB would be appropriate levels under TSCA section 6, whether CARB's cap approach or an average emissions approach would be more appropriate, or whether the additional detailed requirements pertaining to third-party certification and other issues would be appropriate. Several aspects of the CARB ATCM are not in place yet, and EPA is not able to evaluate those aspects. Beyond that, it is entirely possible that some control measure(s) other than the emission cap approach that CARB selected for their ATCM would be appropriate. Especially in view of estimates in the record of nationwide compliance with the ATCM, EPA would want to assess the risk that was likely to remain following compliance with the rule and assess whether one or more of the options under TSCA section 6(a) was more appropriate to address the remaining risk.

In summary, information in the petition and otherwise available to EPA, including health effects, exposure, and economic information, is inadequate to support an evaluation of whether there is an unreasonable risk under TSCA. Therefore, EPA is not granting the specific request in the petition to commence a proceeding under TSCA section 6 to impose the CARB formaldehyde ATCM nationwide.

B. Additional Considerations

Pressed wood products, of which the three composite wood products regulated by CARB are a subset, are a major source of formaldehyde concentrations. Other sources of formaldehyde include smoking, household products, and the use of unvented, fuel-burning appliances like gas stoves or kerosene space heaters (Refs. 16 and 17). Formaldehyde emissions from pressed-wood products are the highest when these products are new and decline over time. Emissions of formaldehyde will increase as the temperature, humidity, and pressed wood surface area increase (Ref. 13).

Several Federal agencies and other entities have regulated or produced guidelines on appropriate air concentrations of formaldehyde. HUD presently limits formaldehyde emissions from plywood and particleboard used in manufactured home construction to 200–300 ppb, and is reviewing proposals to revise those emission limits. Among others, the Agency for Toxic Substances and Disease Registry (ATSDR) has established a Minimal Risk Level (MRL) chronic value of 0.008 ppm/8ppb; the National Institute for Occupational Safety and Health (NIOSH) has established a Recommended Exposure Limit (REL) of 0.016 ppm/16ppb (8–hour Time Weighted Average), and of 0.1 ppm/100ppb (15 minute ceiling); and American Conference of Governmental Industrial Hygienists (ACGIH) has established threshold limit value (TLV)-Ceiling of 0.3 ppm/300 ppb (Ref. 13).

In March 2008, several Federal agencies, including the Department of Health and Human Services (HHS), CDC, U.S. Department of Homeland Security (DHS), FEMA, and EPA finalized a document entitled: ''Formaldehyde Exposure in Homes: A Reference for State Officials to Use in Decision-making,'' which summarizes the environmental health related aspects of formaldehyde exposure in homes and references the government standards in occupational settings (Ref. 14).

Foreign governments, including Japan and the European Union, have also regulated permissible levels of formaldehyde emissions from composite wood products and other building materials (Ref. 2).

EPA previously assessed formaldehyde's cancer risk based on the nasal cavity cancer data in rats and using a linearized multi-staged procedure (for genotoxic carcinogens) (Ref. 4). EPA is conducting a re-assessment/update of the potential cancer risks of formaldehyde through the Integrated Risk Information System (IRIS) process that will consider current human data and other data.

Depending on concentration, it is well recognized that formaldehyde can be an eye, nose, and throat irritant, even when exposure is of relatively short duration. In the indoor environment, sensory reactions and various symptoms as a result of mucous membrane irritation are potential effects, and, while there are large individual differences in the general population, the differences are even greater when hyper-reactive and sensitized people are included in an analysis. EPA acknowledges that there are uncertainties relating to irritation response levels in humans.

In light of information about the hazards of formaldehyde, in combination with the potential for prolonged exposure to potentially problematic levels of formaldehyde by residents in newly constructed housing (Ref. 13), EPA believes it is appropriate, in the Agency's discretion, to initiate a proceeding to better understand the risks from formaldehyde in pressed wood products (including the three types of composite wood regulated by CARB) and to assess various alternatives that EPA might pursue to address such risks. Most of the exposure information presently available to EPA pertains to formaldehyde emissions from pressed wood products in newly built homes (Ref. 13). While emissions from pressed wood products used in new home construction are themselves significant sources of formaldehyde in indoor air, EPA is interested in what other pressed wood sources contribute significantly to formaldehyde concentrations in indoor air. For example, large renovations projects in existing homes, which include a large amount of new pressed wood products, and microenvironments, such as baby cribs built with pressed wood products, could be important sources of exposure to a large number of children and adults.

The available information, guidelines, and regulations span a wide range of permissible formaldehyde levels. EPA believes that it is appropriate to examine these various standards, analyze the risk level for formaldehyde in pressed wood products, and determine the appropriate course of action to reduce risks to human health.

C. EPA's Decision to Initiate a Proceeding to Investigate Formaldehyde in Pressed Wood Products

In sum, the petition does not, as required under TSCA section 21, set forth facts sufficient to establish that it is necessary to initiate a proceeding under TSCA section 6(a) to protect human health against an unreasonable risk of injury by applying the CARB regulation on a national basis. Further, the additional relevant information that EPA has identified does not support initiation of the requested proceeding. However, after considering the facts presented by the petitioners (including the California administrative record), information presented by commenters, and other information available to EPA, EPA has decided to initiate a proceeding to investigate whether and what type of regulatory or other action might be appropriate to protect against risks posed by formaldehyde emitted from pressed wood products.

In parallel with this effort, EPA's ORD will be developing and obtaining external peer review for the IRIS assessment of formaldehyde's cancer and non-cancer risks. OPPTS will coordinate with ORD and other EPA offices as it evaluates risks and options under TSCA, and the results of the IRIS effort will be incorporated into this proceeding if timely available. In addition, the preliminary risk assessment used in the Pesticide Reregistration Program will be considered in the effort to evaluate risks and options under TSCA if timely available, and OPP will also consider the efforts under TSCA, as well as other efforts.

In Fall 2008, EPA plans to issue an advance notice of proposed rulemaking (ANPR) to initiate a proceeding. As part of the ANPR process, EPA will engage stakeholders to contribute to obtaining a better understanding of the available control technologies and approaches, industry practices, and the implementation of CARB's ATCM. Concurrently, EPA plans to develop and conduct an industry survey and initiate development of an exposure assessment and an irritation concern level that could be used for evaluating emissions standards or other approaches. Subsequently, EPA plans to develop an irritation risk assessment, which will receive the appropriate external review, and quantify costs and benefits. At the conclusion of this work, OPPTS anticipates determining whether it should take action, which may include action under TSCA section 6(a) or TSCA section 6(b), or via the development of a voluntary consensus standard or other approaches. As OPPTS evaluates risks and options under TSCA, OPPTS intends to coordinate its efforts with other interested EPA offices and agencies, as well as engage the public and stakeholders.

With respect to the petitioners' request that EPA use TSCA section 6 to apply the CARB rule to manufactured homes, EPA notes that HUD has regulations governing formaldehyde emission levels from plywood and particleboard materials installed in manufactured homes. (See 24 CFR 3280.308.) HUD is in the process of reviewing proposed changes to these regulations to include medium density fiberboard, among other things. HUD is also currently reviewing a proposal to amend its manufactured housing regulations governing formaldehyde to include the standards set forth in the CARB regulation. Section 9(d) of TSCA provides that the Administrator of EPA shall consult and cooperate with other Federal agencies ''for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements.'' 15 U.S.C. 2608(d). Consistent with this provision, EPA will consult and cooperate with HUD as the two agencies work to address formaldehyde emissions from composite wood products.

V. References

The following is a list of the documents that are specifically referenced in this notice and placed in the docket that was established under Docket ID number EPA–HQ–OPPT–2008–0267. For information on accessing these documents in the docket, refer to Unit I.B. Some documents may also be accessed directly using the url provided.

1. Sierra Club, 25 other organizations, and approximately 5,000 individuals. Letter from Tom Neltner, Sierra Club, to Stephen Johnson, Administrator, Environmental Protection Agency. Re: Citizen Petition to EPA Regarding Formaldehyde in Wood Products. March 20, 2008.

2. California Environmental Protection Agency Air Resources Board. Proposed Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products, Staff Report: Initial Statement of Reasons for Proposed Rulemaking. March 9, 2007. *http://www.arb.ca.gov/*

regact/2007/compwood07/compwood07.htm.

3. International Agency for Research on Cancer (IARC). Formaldehyde. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. International Agency for Research on Cancer. Lyon, France. Meeting on June 2–9, 2004, as published by IARC in 2006. Vol. 88. *http://monographs.iarc.fr/ENG/Monographs/vol88/index.php*.

4. EPA, Office of Research and Development. Formaldehyde. Integrated Risk Information System. 1991. *http://www.epa.gov/iris/links.htm*.

5. Chemical Industry Institute of Toxicology (CIIT). Formaldehyde hazard characterization and dose-response assessment for carcinogenicity by the route of inhalation, revised ed. Chemical Industry Institute of Toxicology, Research Triangle Park, NC. 1999.

6. Conolly, R.B., Kimbell, J.S., Janszen, D., and Miller, F., J. Dose-response for formaldehyde–induced cytotoxicity in the human respiratory tract. Regulatory Toxicology and Pharmacology. 35: 32–43. 2002.

7. Conolly, R.B., Kimbell, J.S., Janszen, D., Schlosser, P.M., Kalisak, D., Preston, J., and Miller, F., J. Biologically-motivated computational modeling of formaldehyde carcinogenicity in the F344 rat. Toxicological Sciences. 75:432–447. 2003.

8. Conolly, R.B., Kimbell, J.S., Janszen, D., Schlosser, P.M., Kalisak, D., Preston, J., and Miller, F., J. Human respiratory tract cancer risks of inhaled formaldehyde: Dose-response predictions derived from biologically-motivated computational modeling of a combined rodent and human dataset. Toxicological Sciences. 82: 279–296. 2004.

9. EPA. National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; Effluent Limitations Guidelines and Standards for the Timber Products Point Source Category; List of Hazardous Air Pollutants, Lesser Quantity Designations, Source Category List; Final Rule. **Federal Register** (69 FR 45943, July 30, 2004) (FRL–7634–1). *http://www.epa.gov/ttn/atw/plypart/fr30jy04.pdf*.

10. EPA. National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; List of Hazardous Air Pollutants, Lesser Quantity Designations, Source Category List; Final Rule. **Federal Register** (71 FR 8341, February 16, 2006) (FRL–8028–9). *http://www.epa.gov/ttn/atw/plypart/fr16fe06.pdf*.

11. EPA. National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; Final Rule. **Federal Register** (72 FR 61060, October 29, 2007) (FRL–8482–2). *http://www.epa.gov/ttn/atw/plypart/fr29oc07.pdf*.

12. EPA. Formaldehyde/Paraformaldehyde Risk Assessments; Notice of Availability and Risk Reduction Options; Notice. **Federal Register** (73 FR 21944, April 23, 2008) (FRL–8360–3). *http://www.epa.gov/fedrgstr/EPA-PEST/2008/April/Day-23/p8684.htm*.

13. EPA. Background Document of Technical Information Relevant to the Disposition of the TSCA Section 21 Petition on Formaldehyde. June 2008. Docket ID number EPA–HQ–OPPT–2008–0267.

14. Department of Health and Human Services, Centers for Disease Control and Prevention, Department of Homeland Security, Federal Emergency Management Agency, and EPA. Formaldehyde Exposure in Homes: A Reference for State Officials to Use in Decision-Making. March 2008. *http://www.cdc.gov/nceh/ehhe/trailerstudy/compendium.htm*.

15. EPA. Formaldehyde: Preliminary Risk Assessment for the Registration Eligibility Decision (RED). DP Barcode: 348474, April 7, 2008. Docket ID number EPA–HQ–OPP–2008–0121. *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPP-2008-0121*.

16. CPSC. 1997. An Update On Formaldehyde: 1997 Revision. Consumer Product Safety Commission, Washington, DC, CPSC Doc. #725 *http://www.cpsc.gov/cpscpub/pubs/725.html*.

17. EPA. 2007. Indoor Air Quality (IAQ), Pollutants and Sources of Indoor Air Pollution, Formaldehyde/Pressed Wood Products, Office of Radiation and Indoor Air (ORIA), Indoor Environments Division, Washington, DC, Updated November 14, 2007. *http://www.epa.gov/iaq/formalde.html#Levels%20in%20Homes*.

List of Subjects

Environmental protection, Composite wood products, Formaldehyde, Housing, Toxic Substance Control Act (TSCA).

Dated: June 21, 2008.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. E8–14618 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2008–0102; FRL–8369–6]

Exposure Modeling Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: An Exposure Modeling Public Meeting (EMPM) will be held for one day on July 22, 2008. This notice announces the location and time for the meeting and sets forth the tentative agenda topics.

DATES: The meeting will be held on July 22, 2008 from 9:00 am to 4:00 pm.

To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATON CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

ADDRESSES: The meeting will be held at Environmental Protection Agency, Office of Pesticide Programs (OPP), One Potomac Yard (South Building), 1st Floor South Conference Room, 2777 S. Crystal Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Michael Barrett, Environmental Fate and Effects Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–-6391; fax number: (703) 305–6309]; e-mail address: *barrett.michael@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA), the Federal Food, Drug and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have nay questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket ID number EPA–HQ–OPP–2008–0102.

Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*.

II. Background

On a triannual interval, an Exposure Modeling Public Meeting will be held for presentation and discussion of current issues in modeling pesticide fate, transport, and exposure in support of risk assessment in a regulatory context. Meeting dates and abstract requests are announced through the ''empmlist'' forum on the LYRIS list server at *https://lists.epa.gov/read/all_forums/*.

III. How Can I Request to Participate in this Meeting?

You may submit a request to participate in this meeting to the person listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered CBI. Requests to participate in the meeting, identified by docket ID number EPA–HQ–OPP–2008–0102, must be received on or before July 14, 2008.

IV. Tentative Topics for the Meeting

1. General Theme: Terrestrial Modeling

2. Specific Topics:

a. Discussion of PlantEX Model

b. Overview of T-REX and T-HERPES

c. TIM Model (Avian Probabilistic Model)

d. Chloropicrin Manufacturing Task Force Presentation on Chain 2-D Model

e. Riparian Ecosystem Management Model (REMM) and Runoff Study to Validate Model

f. Fumigant Emission Physical Factors and Measures for Mitigating Exposure Incidences

List of Subjects

Environmental protection, Modeling, Monitoring, Pesticides, Pest.

Dated: June 17, 2008.

Arthur Jean Williams,

Acting Director, Environmental Fate and Effects Division, Office of Pesticide Programs.

[FR Doc. E8–14514 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2006–0341; FRL–8370–4]

Modification of the Voluntary Children's Chemical Evaluation Program; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA will hold a public meeting to give the stakeholders in the Voluntary Childrens Chemical Evaluation Program (VCCEP) and interested members of the public an opportunity to comment on the modifications the Agency intends to make to VCCEP. The modifications are based on the responses the Agency received to its request for comment on the implementation of the VCCEP pilot. The modifications will primarily address the timeliness and efficiency issues of the program in order to increase its productivity and ability to provide information to the public on the potential risks to children of exposure to certain chemicals. The meeting will also provide the public with an opportunity to comment on the use of the modified VCCEP approach to address certain data and assessment needs identified in EPA's review of high production volume (HPV) and mid production volume (MPV) chemicals under its Chemical Assessment and Management Program (ChAMP).

DATES: The meeting will be held on Tuesday, July 22, 2008, from 9 a.m. to 11 a.m.

Requests to participate in the meeting must be received on or before July 17, 2008.

To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATON CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, 1201 Constitution Ave., NW., Rm. 1153, Washington, DC 20460.

Requests to participate in the meeting, identified by docket identification (ID) number EPA–HQ–OPPT–2006–0341, may be submitted to the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Catherine Roman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8157; e-mail address: *roman.catherine@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of particular interest to those chemical manufacturers (including importers) who produce or import chemical substances that are subject to the Toxic Substances Control Act (TSCA), in particular those chemical manufacturers (including importers) that are sponsoring chemicals in VCCEP, individuals or groups concerned with chemical testing and childrens health, and animal welfare groups. Because other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket ID number EPA–HQ–OPPT–2006–0341. All documents in the docket are listed in the docket's index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301

Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*.

II. Background

VCCEP was designed to collect health effects, exposure, and risk information on chemicals to which children are likely to be exposed, and to make that information available to the public so the public may better understand the potential health risks to children associated with certain chemical exposures, and to allow EPA and others to evaluate the risks of these chemicals so that mitigation measures may be taken as appropriate. EPA announced VCCEP in December 2000 (Ref. 1) and requested chemical manufacturers and importers to participate in a pilot of the program by voluntarily sponsoring their chemical if it were among those selected by EPA. The pilot began in 2001 when companies volunteered to sponsor their chemicals in response to EPAs request.

In 2006, at what was approximately the midpoint in the implementation of the pilot phase of VCCEP, EPA sought to evaluate how well the pilot was meeting the objectives of VCCEP. To that end, EPA requested that the public submit comments on their experience with the pilot phase of VCCEP and its opinions on the progress of the pilot phase to date (Ref. 2). Additionally, EPA developed a list of questions in order to focus comments on certain features of the VCCEP pilot on which the Agency particularly wanted input. The comments EPA received were summarized and made available to the public on the VCCEP website (*http://www.epa.gov/oppt/vccep*). Some of the main comments concerned the timeliness and efficiency of the program, the chemicals selected for the pilot program, the use of a tiered approach to testing, and the use of a Peer Consultation process to review chemical assessments. Based on those comments and also internal Agency discussions, EPA has developed a list of modifications that it believes will improve the future performance of VCCEP. Although the VCCEP program will continue to operate primarily as described in the **Federal Register** notice launching the program (Ref. 1), certain modifications to address the main concerns of the Agency, stakeholders and the public are being contemplated by EPA. EPA wants to share and discuss the contemplated modifications with the VCCEP stakeholders and the public and listen to any additional comments. Therefore, EPA will hold a public meeting on July 22, 2008, at EPA headquarters in Washington, DC. The modifications which will be the basis for the discussions at the public meeting are as follows:

1. *Chemical selection*. To address the concern that the chemicals covered in the VCCEP Pilot were a set of particularly well-studied chemicals for which, in most cases, little additional assessment was needed, future VCCEP chemicals will primarily be selected from chemicals that, when assessed as part of ChAMP, are identified as being of special concern and as presenting hazard/exposure data needs that are relevant to characterizing risks to children. (A more detailed description of ChAMP is provided in this unit as well as at (*http://www.epa.gov/ChAMP)*. Chemicals that also meet the original VCCEP chemical selection criteria which were evidence of presence in human tissues and in relevant environmental media (e.g., indoor air, drinking water, and food) will be a particular focus of future VCCEP activity.

2. *Changes to the assessment approach*.

• To ensure timely completion of chemical assessments, specific due dates for sponsor assessment submissions and peer consultations will be established in sponsor commitments, including timelines for responding to follow-up actions/requests.

• To bring concerns for potential chemical risks to prompt resolution, EPA will indicate in its Tier 1 Data Needs Decision when it believes it is reasonable to combine Tiers 2 and 3 as used in the VCCEP Pilot into a single tier. EPA recognizes that a three tier approach may be acceptable when the sponsor can demonstrate that it is sound scientifically and that a delay in the public availability of Tier 3 data would not have potential public health impacts.

3.*Peer consultation modifications*. Under the modified approach envisioned by EPA, the following points would be agreed to in advance by EPA and the sponsoring company or the VCCEP approach will not be used for purposes of obtaining needed information.

• The peer consultation process will remain the mechanism to review sponsor-generated assessments and the sponsor will be responsible for contracting with an independent third party to manage the peer consultation and will bear the associated financial burdens.

• Distinguishing between ''data needs'' and ''data gaps,'' which was a useful outcome of the VCCEP Pilot, will be used in VCCEP peer consultations.

• So that sponsors can better address concerns identified in the peer consultation before EPA develops a Data Needs Decision, the sponsor will promptly develop revised assessments that respond to issues identified in the Peer Consultation Meeting Report and make them publicly available. The sponsor will amend its assessments within 90 days after the Peer Consultation Meeting Report is made available to them. EPA will use the amended assessments and the Peer Consultation Meeting Report to make its Data Needs Decision within 90 days of receipt of the revised assessments. The sponsor will then have 4 months after the receipt of the Data Needs Decision, as is current practice in the VCCEP Pilot, to decide whether to commit to the next tier of assessment, if necessary.

The meeting on July 22, 2008, will also provide the public with an opportunity to comment on the use of the modified VCCEP approach to address certain data and assessment needs identified in EPA's review of HPV and MPV chemicals under ChAMP, including environmental toxicity, environmental fate, and aspects that may go beyond mammalian toxicity. ChAMP was established by EPA as a mechanism to partially address the Security and Prosperity Partnership (SPP) commitments announced by the United States, Canada, and Mexico in Montebello, Canada in August 2007. These commitments included a number of national and regional commitments to trilateral cooperation in the assessment and management of chemicals in North America. The United States has committed, by 2012, to assess and initiate needed actions on chemicals produced above 25,000 pounds per year (lb./yr.) in the country. High production volume (HPV) chemicals are manufactured and imported in quantities greater than 1,000,000 lb./yr. and moderate production volume (MPV) chemicals are manufactured and imported in quantities greater than

25,000 lb./yr. but less than 1,000,000 lb./yr. EPA's ongoing efforts under ChAMP to screen and prioritize the risks of chemicals will be a major component of EPA's efforts to meet its SPP commitments.

EPA believes that an adaptation of the modified VCCEP approach could provide a flexible framework to further evaluate certain chemicals identified by EPA in its ChAMP screening-level assessments as presenting special concerns and associated follow-up action involving hazard/exposure data development or assessment.

EPA believes that in most instances, the detailed evaluation of SPP follow-up cases under the modified VCCEP approach should generally begin at Tier 1. Sponsor-developed assessments should build on EPA's SPP screening-level assessments, consider EPA recommended follow-up actions (including conducting higher tier tests specifically identified as priorities by EPA on the basis of its initial assessment), and include a more highly developed quantification of exposures.

III. How Can I Request to Participate in this Meeting?

You may submit a request to participate in this meeting to the technical person listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered CBI. Requests to participate in the meeting, identified by docket ID number EPA–HQ–OPPT–2006–0341, must be received on or before July 17, 2008.

IV. References

1. EPA. Voluntary Children's Chemical Evaluation Program; Notice. **Federal Register** (65 FR 81699, December 26, 2000) (FRL–6758–5). Available on-line at: *http://www.epa.gov/fedrgstr*.

2. EPA. Implementation of the Pilot Voluntary Children's ChemicalEvaluation Program; Request for Comment; Notice. **Federal Register** (71 FR 67121, November 20, 2006) (FRL–8057–1). Available on-line at: *http://www.epa.gov/fedrgstr*.

List of Subjects

Environmental protection, Chemicals, Child Health.

Dated: June 20, 2008.

James B. Gulliford

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances

[FR Doc. E8–14528 Filed 6–26–08; 8:45 am]

BILLING CODE 6560–50–S

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Amendment to Sunshine Act Meeting

AGENCY: Farm Credit Administration.

SUMMARY: Pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), the Farm Credit Administration gave notice on June 24, 2008 (73 FR 35687) of the regular meeting of the Farm Credit Administration Board (Board) scheduled for July 10, 2008. This notice is to amend the agenda by adding an item to the open session of that meeting.

FOR FURTHER INFORMATION CONTACT: Roland E. Smith, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090.

SUPPLEMENTARY INFORMATION: This meeting of the Board was open to the public (limited space available). In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The agenda for July 10, 2008, is amended by adding the following item to the open session as follows:

Open Session

A. Reports

- Effects of the Midwest Flooding

Dated: June 20, 2008.

Roland E. Smith,

Secretary, Farm Credit Administration Board.

[FR Doc. 08–1396 Filed 6–25–08; 12:47pm]

BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

June 23, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to take this opportunity to (PRA) of 1995 (PRA), Public Law No. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. Subject to the PRA, no person shall be subject to any penalty for failing to comply with a collection of information that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written PRA comments should be submitted on or before August 26, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Interested parties may submit all PRA comments by e-mail or U.S. post mail. To submit your comments by e-mail, send them to *PRA@fcc.gov* and/or *Cathy.Williams@fcc.gov.* To submit your comments by U.S. mail, mark them to the attention of Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection(s), contact Cathy Williams at (202) 418–2918 or send an e-mail to *PRA@fcc.gov* and/or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0061.

Title: Annual Report of Cable Television Systems.

Form Number: FCC Form 325.

Type of Review: Revision of a currently approved collection.

Respondents: Business and other for-profit.

Number of Respondents and Responses: 1,200 respondents; 1,200 responses.

Estimated Time per Response: 2.166 hours.

Frequency of Response: Annual reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Sections 4(i), 601 and 602 of the Commissions Act of 1934, as amended.

Total Annual Burden: 2,599 hours.

Total Annual Costs: None.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission made revisions/refinements to FCC

Form 325 to accommodate systems using technologies other than coaxial cable (Section II,4). Previously, the number of these filers was very small. Now the portion of the sample is becoming significant. These revisions/refinements to Form 325 will allow the form to be filed electronically by these filers, avoiding a significant cost. Refinements are also made to the form to eliminate instances where potential subscribers are double counted (Section II,2). This occurs where a competing system enters the market and reports as such. These refinements impose no significant new requirement and will reduce aggregate filing costs by simplifying filing for overbuilders and permitting electronic filing for the increasing number of competing service providers.

The FCC uses Form 325 ''Annual Report of Cable Television'' to solicit basic operational information from a sample of cable systems nationwide, including: the operator's name and address; system-wide capacity and frequency information; channel usage; and number of subscribers. Operators of every operational cable television system are required to complete the form to verify, correct and/or furnish the Commission with the most current information on their respective cable systems.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–14640 Filed 6–26–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension

AGENCY: Federal Trade Commission (''Commission'' or ''FTC'').

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (''OMB'') for review, as required by the Paperwork Reduction Act (''PRA''). The FTC is seeking public comments on its proposal to extend through July 31, 2011, the current PRA clearance for information collection requirements contained in the Commission's Gramm-Leach-Bliley Financial Privacy Rule (''GLB Privacy Rule'' or ''Rule''). The current clearance expires on July 31, 2008.

DATES: Comments must be submitted on or before July 28, 2008.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''Paperwork Comment: FTC File No. P085405'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope and should be mailed or delivered to the following address: Federal Trade Commission, Room H-135 (Annex J), 600 Pennsylvania Ave., N.W., Washington, D.C. 20580. The Commission is requesting that any comment filed in paper form be sent by courier or overnight service, if possible because U.S. postal mail in the Washington area and at the FTC is subject to delay due to heightened security precautions. Moreover, because paper mail in the Washington area and at the FTC is subject to delay, please consider submitting your comments in electronic form, as prescribed below. If, however, the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document must be clearly labeled ''Confidential.''[1]

Comments filed in electronic form should be submitted by following the instructions on the web-based form at (*https://secure.commentworks.com/ftc-glbprivacyrulepra*) and following the instructions on the web-based form. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the (*https://secure.commentworks.com/ftc-glbprivacyrulepra*) weblink. If this notice appears at *www.regulations.gov*, you may also file an electronic comment through that website. The Commission will consider all comments that *www.regulations.gov* forwards to it.

All comments should additionally be submitted to: Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission. Comments should be submitted via facsimile to (202) 395-6974 because U.S. Postal Mail is subject to lengthy delays due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments will be considered by the Commission and will be available to the public on the FTC website, to the extent practicable, at *www.ftc.gov*. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at (*http://www.ftc.gov/ftc/privacy.shtm*).

FOR FURTHER INFORMATION CONTACT: Kellie Cosgrove Riley, Senior Attorney, Division of Privacy and Identity Protection, Bureau of Consumer Protection, (202) 326-2252, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

SUPPLEMENTARY INFORMATION: On April 2, 2008, the FTC sought comment on the information collection requirements associated with the GLB Privacy Rule, 16 CFR Part 313 (OMB Control Number 3084-0121). *See* 73 FR 17980. No comments were received. Pursuant to the OMB regulations, 5 CFR Part 1320, that implement the PRA, 44 U.S.C. 3501-3521, the FTC is providing this second opportunity for public comment while seeking OMB approval to extend the existing PRA clearance for the Rule. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before July 28, 2008.

The GLB Privacy Rule is designed to ensure that customers and consumers, subject to certain exceptions, will have access to the privacy policies of the financial institutions with which they conduct business. As mandated by the Gramm-Leach-Bliley Act, 15 U.S.C. 6801-6809, the Rule requires financial institutions to disclose to consumers: (1) initial notice of the financial institution's privacy policy when establishing a customer relationship with a consumer and/or before sharing a consumer's non-public personal information with certain nonaffiliated third parties; (2) notice of the consumer's right to opt out of information sharing with such parties; (3) annual notice of the institution's privacy policy to any continuing customer; and (4) notice of changes in the institution's practices on information sharing. These requirements are subject to the PRA. The Rule does not require recordkeeping.

Estimated annual hours burden: As noted in the original burden estimate for the GLB Privacy Rule, determining the paperwork burden of the Rule's disclosure requirements is very difficult because of the highly diverse group of

[1] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

affected entities, consisting of financial institutions not regulated by a federal financial regulatory agency. *See* 15 U.S.C. 6805 (committing to the Commission's jurisdiction entities that are not specifically subject to another agency's jurisdiction).

The burden estimates represent the FTC staff's best assessment, based on its knowledge and expertise relating to the financial institutions subject to the Commission's jurisdiction under this law. To derive these estimates, staff considered the wide variations in covered entities. In some instances, covered entities may make the required disclosures in the ordinary course of business, apart from the GLB Privacy Rule. In addition, some entities may use highly automated means to provide the required disclosures, while others may rely on methods requiring more manual effort. The burden estimates shown below include the time that may be necessary to train staff to comply with the regulations. These figures are averages based on staff's best estimate of the burden incurred over the broad spectrum of covered entities.

Staff retains its prior estimate of the number of entities each year that will address the GLB Privacy Rule for the first time (5,000) and its estimate of established entities already familiar with the Rule (100,000). While the number of established entities familiar with the Rule would theoretically increase each year with the addition of new entrants, staff retains its previous estimate of established entities given that a number of the established entities will close in any given year, and also given the difficulty of establishing a more precise estimate. Staff's burden estimates for new entrants and established entities are detailed in the charts below.

Start-up hours and labor costs for new entrants:

Event	*Hourly wage and labor category**	*Hours per Respondent*	*Approx. Number of Respondents*	*Approx. Total Annual Hrs.*	*Approx. Total Labor Costs*
Reviewing internal policies and developing GLBA-implementing instructions**	$31.66 managerial/professional	20	5,000	100,000	$3,166,000
Creating disclosure document or electronic disclosure (including initial, annual, and opt out disclosures)	$14.71 clerical	5	5,000	25,000	$367,750
	$32.82 professional/technical	10		50,000	$1,641,000
Disseminating initial disclosure (including opt out notices)	$14.71 clerical	15	5,000	75,000	$1,103,250
	$32.82 professional/technical	10		50,000	$1,641,000
Total				300,000	$7,919,000

* Staff calculated labor costs by applying appropriate hourly cost figures to burden hours. The hourly rates used were based on mean wages for managerial/professional time (*e.g.*, compliance evaluation and/or planning), professional/technical time (*e.g.*, designing and producing notices, reviewing and updating information systems), and clerical time (*e.g.*, reproduction tasks, filing, and, where applicable to the given event, typing or mailing). *See* BLS National Compensation Survey, June 2006, Table 1, available at *http://www.bls.gov/ncs/ocs/sp/ncbl0910.pdf* (Management, professional, and related; office and administrative support) and BLS Occupational Employment and Wages 2006,Table 2, available at *http://www.bls.gov/news.release/pdf/ocwage.pdf* (professional, scientific, and technical services - business and financial operations). Labor cost totals reflect solely that of the commercial entities affected. Staff assumes that the time required of consumers to respond affirmatively to respondents' opt-out programs (be it manually or electronically) would be minimal.

** Reviewing instructions includes all efforts performed by or for the respondent to: determine whether and to what extent the respondent is covered by an agency collection of information, understand the nature of the request, and determine the appropriate response (including the creation and dissemination of document and/or electronic disclosures).

Burden hours and costs for established entities:

Burden for established entities already familiar with the Rule predictably would be less than for start-up entities because start-up costs, such as crafting a privacy policy, are generally one-time costs and have already been incurred. Staff's best estimate of the average burden for these entities is as follows:

Event	*Hourly wage and labor category**	*Hours per Respondent*	*Approx. Number of Respondents***	*Approx. Total Annual Hours*	*Approx. Total Labor Costs*
Reviewing GLBA-implementing policies and practices	$31.66 managerial/professional	4	70,000	280,000	$8,864,800

Event	Hourly wage and labor category*	Hours per Respondent	Approx. Number of Respondents**	Approx. Total Annual Hours	Approx. Total Labor Costs
Disseminating annual disclosure	$14.71 clerical	15	70,000	1,050,000	$15,445,500
	$32.82 professional/technical	5		350,000	$11,487,000
Changes to privacy policies and related disclosures	$14.71 clerical	15	1,000	15,000	$220,650
	$32.82 professional/technical	5		5,000	$164,100
Total				1,700,000	$36,182,050

* Staff calculated labor costs by applying appropriate hourly cost figures to burden hours; labor cost totals reflect solely that of the commercial entities affected. The hourly rates used were based on mean wages for managerial/professional time (*e.g.*, compliance evaluation and/or planning), professional/technical time (*e.g.*, designing and producing notices, reviewing and updating information systems), and clerical time (*e.g.*, reproduction tasks, filing, and, where applicable to the given event, typing or mailing). *See* BLS National Compensation Survey, June 2006, Table 1, available at *http://www.bls.gov/ncs/ocs/sp/ncbl0910.pdf* (Management, professional, and related; office and administrative support) and BLS Occupational Employment and Wages 2006,Table 2, available at *http://www.bls.gov/news.release/pdf/ocwage.pdf* (professional, scientific, and technical services - business and financial operations). Consumers have a continuing right to opt-out, as well as a right to revoke their opt-out at any time. When a respondent changes its information sharing practices, consumers are again given the opportunity to opt-out. Again, staff assumes that the time required of consumers to respond affirmatively to respondents' opt-out programs (be it manually or electronically) would be minimal.

** The estimate of respondents is based on the following assumptions: (1) 100,000 respondents, approximately 70% of whom maintain customer relationships exceeding one year, (2) no more than 1% (1,000) of whom make additional changes to privacy policies at any time other than the occasion of the annual notice; and (3) such changes will occur no more often than once per year.

As calculated above, the total annual PRA burden hours and labor costs for all affected entities in a given year would be 2,000,000 hours and $44,101,000, respectively.

Estimated Capital/Other Non-Labor Costs Burden: Staff believes that capital or other non-labor costs associated with the document requests are minimal. Covered entities will already be equipped to provide written notices (*e.g.*, computers with word processing programs, typewriters, copying machines, mailing capabilities). Most likely, only entities that already have on-line capabilities will offer consumers the choice to receive notices via electronic format. As such, these entities will already be equipped with the computer equipment and software necessary to disseminate the required disclosures via electronic means.

David C. Shonka,

Acting General Counsel.

[FR Doc. E8–14621 Filed 6–26–08: 8:45 am]

[BILLING CODE: 6750–01–S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–0488]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Restriction on Travel of Persons (OMB Control No. 0920–0488)—Reinstatement without Change—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention is requesting OMB approval to reinstate without change the information collection request, Restriction on Travel of Persons (OMB Control No. 0920–0488). This information collection request expired on March 31, 2007.

CDC is authorized to collect this information under 42 CFR 70.5 (certain communicable diseases; special requirements). This regulation requires that any person who is in the communicable period for cholera, plague, smallpox, typhus, or yellow fever or having been exposed to any such disease is in the incubation period thereof, to apply for and receive a permit from the Surgeon General or his authorized representative in order to travel from one State or possession to another.

Control of disease transmission within the States is considered to be the province of State and local health authorities, with Federal assistance being sought by those authorities on a cooperative basis without application of Federal regulations. The regulations in 42 part 70 were developed to facilitate Federal action in the event of large outbreaks requiring a coordinated effort involving several States, or in the event of inadequate local control. While it is not known whether, or to what extent situations may arise in which these regulations would be invoked, contingency planning for domestic emergency preparedness is now commonplace. Should these situations arise, CDC will use the reporting and recordkeeping requirements contained in the regulations to carry out quarantine responsibilities as required by law.

The only cost to respondents is their time to submit the application materials. The estimated annualized burden for this data collection is 3,600 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Regulation	Respondent	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
42 CFR 70.3 Application to the State of Destination for a permit.	Traveler	2,000	1	15/60
	Attending physician	2,000	1	15/60
42 CFR 70.3 Copy of material submitted by applicant and permit issued by State health authority.	State health authority	8	250	6/60
42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel.	Master of a vessel or person in charge of conveyance.	1,500	1	15/60
42 CFR 70.4 Copy of material submitted or State or local health authority under this provision.	State health authority	20	75	6/60
42 CFR 70.5 Application for a permit to move from State to State while in the communicable period.	Traveler	3,750	1	15/60
	Attending physician	3,750	1	15/60

Dated: June 20, 2008.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–14589 Filed 6–26–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Elimination of Health Disparities Through Translation Research (Panel C), Funding Opportunity Announcement (FOA), CD08–001

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 aforementioned meeting:

Time and Date: 10 a.m.–5 p.m., July 16, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of ''Elimination of Health Disparities through Translation Research (Panel C), FOA CD08–001.''

Contact Person for More Information: Susan B. Stanton, D.D.S., Scientific Review Administrator, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone (404) 639–4640.

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: June 20, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–14580 Filed 6–26–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Elimination of Health Disparities through Translation Research (Panel B), Funding Opportunity Announcement (FOA), CD08–001

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 aforementioned meeting:

Time and Date: 10 a.m.–5 p.m., July 15, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of ''Elimination of Health Disparities through Translation Research (Panel B), FOA CD08–001.''

Contact Person for More Information: Susan B. Stanton, D.D.S., Scientific Review Administrator, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone (404) 639–4640.

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: June 20, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–14587 Filed 6–26–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2898–PN]

Medicare and Medicaid Programs; The Joint Commission for Continued Deeming Authority for Ambulatory Surgical Centers

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of a deeming application from the Joint Commission for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to

participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. e.s.t. on July 27, 2008.

ADDRESSES: In commenting, please refer to file code CMS–2898–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically*. You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the file code to find the document accepting comments.

2. *By regular 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–2898–PN, P.O. Box 8013, Baltimore, MD 21244–__.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail*. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2898–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier*. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey (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.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

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.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Laura Weber, (410) 786–0227, Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) authorizes the Secretary to establish distinct criteria for facilities seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR Part 489 and those pertaining to activities relating to the survey and certification of facilities are at Part 488. Part 416 specifies the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for ASCs.

Generally, in order to enter into an agreement with the Medicare program, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in Part 416. Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that, if an ASC demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those ASCs as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under Part 488, subpart A must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). Section 488.8(d)(3) requires accrediting organizations to reapply for continued deeming authority every 6 years or sooner as determined by us.

The Joint Commission's term of approval as a recognized accreditation program for ASCs expires December 20, 2008.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act and § 488.8(a) of the regulations require that our findings concerning review and reapproval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's: requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the

nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Joint Commission's request for continued deeming authority for ASCs. This notice also solicits public comment on whether the Joint Commission's requirements meet or exceed the Medicare conditions for coverage for ASCs.

III. Evaluation of Deeming Authority Request

The Joint Commission submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for ASCs. This application was determined to be complete on May 2, 2008. Under section 1865(b)(2) of the Act and § 488.8 (Federal review of accrediting organizations), our review and evaluation of the Joint Commission will be conducted in accordance with, but not necessarily limited to, the following factors:

• The equivalency of the Joint Commission's standards for an ASC as compared with CMS' ASC conditions for coverage.

• The Joint Commission's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of the Joint Commission's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ The Joint Commission's processes and procedures for monitoring ASCs found out of compliance with the Joint Commission's program requirements. These monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.7(d).

++ The Joint Commission's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ The Joint Commission's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of the Joint Commission's staff and other resources, and its financial viability.

++ The Joint Commission's capacity to adequately fund required surveys.

++ The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ The Joint Commission's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35 *et seq.*).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866 (September 1993, Regulatory Planning and Review, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 10, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–14679 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2897–PN]

Medicare and Medicaid Programs; Application by the Accreditation Association for Ambulatory Health Care for Continued Deeming Authority for Ambulatory Surgical Centers

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of a deeming application from the Accreditation Association for Ambulatory Health Care (AAAHC) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. e.s.t. on July 27, 2008.

ADDRESSES: In commenting, please refer to file code CMS–2897–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. Electronically. You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the file code to find the document accepting comments.

2. *By regular 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–2897–PN, P.O. Box 8013, Baltimore, MD 21244____.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2897–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey (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.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

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.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Aviva Walker-Sicard, (410) 786–8648, Patricia Chmielewski, (410) 786–6899

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) authorizes the Secretary to establish distinct criteria for facilities seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at part 488. Part 416 specifies the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for ASCs.

Generally, in order to enter into an agreement with the Medicare program, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416. Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative to surveys by State agencies, which is accreditation.

Section 1865(b)(1) of the Act provides that, if an ASC demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those ASCs as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under part 488, subpart A must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). Section 488.8(d)(3) requires accrediting organizations to reapply for continued deeming authority every 6 years or sooner as determined by us.

AAAHC's term of approval as a recognized accreditation program for ASCs expires December 20, 2008.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act and § 488.8(a) of the regulations require that our findings concerning review and reapproval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's: Requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of AAAHC's request for continued deeming authority for ASCs. This notice also solicits public comment on whether AAAHC's requirements meet or exceed the Medicare conditions for coverage for ASCs.

III. Evaluation of Deeming Authority Request

AAAHC submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for ASCs. This application was determined to be complete on May 2, 2008. Under section 1865(b)(2) of the Act and § 488.8 (Federal review of accrediting organizations), our review and evaluation of AAAHC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAAHC's standards for an ASC as compared with CMS' ASC conditions for coverage.
- AAAHC's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of AAAHC's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ AAAHC's processes and procedures for monitoring ASCs found out of compliance with AAAHC's program requirements. These monitoring procedures are used only when AAAHC identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.7(d).

++ AAAHC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ AAAHC's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of AAAHC's staff and other resources, and its financial viability.

++ AAAHC's capacity to adequately fund required surveys.

++ AAAHC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ AAAHC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35 *et seq.*).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866 (September 1993, Regulatory Planning and Review, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354)), the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 10, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–14647 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1400–GNC]

RIN 0938–AP34

Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During Fiscal Year 2009

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: General notice with comment period.

SUMMARY: This general notice with comment period describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries (FIs) and carriers in the administration of the Medicare program. The results of these evaluations are considered whenever we enter into, renew, or terminate a FI agreement, carrier contract, or take other contract actions, for example, assigning or reassigning providers or services to a FI or designating regional or national intermediaries. We are requesting public comment on these criteria and standards.

DATES: *Effective Date:* The criteria and standards are effective on October 1, 2008.

Comment Date: To be assured consideration, comments must be received no later than 5 p.m. on August 26, 2008.

ADDRESSES: In commenting, please refer to file code CMS–1400–GNC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular 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–1400–GNC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1400–GNC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. (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.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lee Ann Crochunis, (410) 786–3362.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 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. Medicare Part A—Hospital Insurance

Under section 1816 of the Social Security Act (the Act), public or private organizations and agencies participate in the administration of Part A (Hospital Insurance) of the Medicare program under agreements with CMS. These agencies or organizations, known as fiscal intermediaries (FIs), determine whether medical services are covered under Medicare, determine correct payment amounts and then make payments to the health care providers (for example, hospitals, skilled nursing facilities (SNFs), and community mental health centers) on behalf of the beneficiaries. Section 1816(f) of the Act requires us to develop criteria, standards, and procedures to evaluate an FI's performance of its functions under its agreement.

Section 1816(e)(4) of the Act requires us to designate regional agencies or organizations, which are already Medicare FIs under section 1816 of the Act, to perform claim processing functions for freestanding home health agency (HHA) claims. We refer to these organizations as Regional Home Health Intermediaries (RHHIs) under 42 CFR 421.117.

The evaluation of FI performance is part of our contract management process. These evaluations need not be limited to the current fiscal year (FY), other fixed term basis, or agreement term.

B. Medicare Part B—Supplementary Medical Insurance

Under section 1842 of the Act, we are authorized to enter into contracts with carriers to fulfill various functions in the administration of Part B, Supplementary Medical Insurance of the Medicare program. Beneficiaries, physicians, and suppliers of services submit claims to these carriers. The carriers determine whether the services are covered under Medicare and the amount payable for the services or supplies, and then make payment to the appropriate party.

Under section 1842(b)(2) of the Act, we are required to develop criteria, standards, and procedures to evaluate a carrier's performance of its functions under its contract. Evaluations of Medicare fee-for-service (FFS) contractor performance need not be limited to the current Fiscal Year (FY), other fixed term basis, or contract term. The evaluation of carrier performance is part of our contract management process.

C. Development and Publication of Criteria and Standards

In addition to the statutory requirements, § 421.120, § 421.122, and § 421.201, provide for publication of a **Federal Register** notice to announce the criteria and standards for FIs and carriers before the beginning of each evaluation period. In the October 1, 2007 **Federal Register** (72 FR 55775), we published a general notice with comment period the current criteria and standards for FIs and carriers.

To the extent possible, we make every effort to publish the criteria and standards before the beginning of the FY, which is October 1. If we do not publish a **Federal Register** notice before the new FY begins, readers may presume that until and unless notified otherwise, the criteria and standards that were in effect for the previous FY remain in effect.

In those instances in which we are unable to meet our goal of publishing the subject **Federal Register** notice before the beginning of the FY, we may publish the criteria and standards notice at any subsequent time during the year. If we publish a notice in this manner, the evaluation period for the criteria and standards that are the subject of the notice will be effective beginning on the first day of the first month following publication of this notice in the **Federal Register**. Any revised criteria and standards will measure performance prospectively; that is, any new criteria and standards in the notice will be applied only to performance after the effective date listed on the notice.

It is not our intention to revise the criteria and standards that will be used during the evaluation period once this information is published in a **Federal Register** notice. However, on occasion, either because of administrative action or statutory mandate, there may be a need for changes that have a direct impact on the criteria and standards previously published, or that require the addition of new criteria or standards, or that cause the deletion of previously published criteria and standards. If we make these changes, we will publish a **Federal Register** notice before implementation of the changes. In all instances, necessary manual issuances will be published to ensure that the criteria and standards are applied uniformly and accurately. Also, as in previous years, this **Federal Register** notice will be republished and the effective date revised if changes are warranted as a result of the public comments received on the criteria and standards.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. Section 911 of the MMA establishes the Medicare FFS Contracting Reform (MCR) initiative that is being implemented over the next several years. This provision requires that we use competitive procedures to replace our current FIs and carriers with Medicare Administrative Contractors (MACs). The MMA requires that we compete and transition all work to MACs by October 1, 2011.

FIs and carriers will continue administering Medicare FFS work as may be required until the final competitively selected MAC is up and operating. We will continue to develop and publish standards and criteria for use in evaluating the performance of FIs and carriers as long as these types of contractors exist.

II. Analysis of and Response to Public Comments Received on FY 2008 Criteria and Standards

We received three comments in response to the October 1, 2007 **Federal Register** general notice with comment. All comments were reviewed, but none necessitated reissuance of the FY 2008 Criteria and Standards. Comments submitted did not pertain specifically to the FY 2007 Criteria and Standards.

III. Criteria and Standards—General

Basic principles of the Medicare program are to pay claims promptly and accurately, and to foster good beneficiary and provider relations. Contractors must administer the Medicare program efficiently and economically. The goal of performance evaluation is to ensure that contractors meet their contractual obligations. We measure contractor performance to ensure that contractors do what is required of them by statute, regulation, contract, and our directives.

We have developed a contractor oversight program for FY 2009 that outlines what is expected of the contractor; measures the performance of the contractor; evaluates the contractor's performance against those expectations; and provides for appropriate contract action based upon the evaluation of the contractor's performance.

As a means to monitor the accuracy of Medicare FFS payments, we have established the Comprehensive Error Rate Testing (CERT) program that measures and reports error rates for claims payment decisions made by carriers and FIs. Since November 2003, the CERT program has been measuring and reporting claims payment error rates for each individual carrier. FI-specific rates became available November 2004. These rates measure not only how well contractors are doing at implementing automated review edits and identifying which claims to subject to manual medical review, but they also measure the impact of the contractor's provider outreach/education, as well as the effectiveness of the contractor's provider call center(s). We will use these contractor-specific error rates as a means to evaluate a contractor's performance.

Several times throughout this notice, we refer to the appropriate reading level of letters, decisions, or correspondence that are mailed or otherwise transmitted to Medicare beneficiaries from intermediaries or carriers. In those instances, appropriate reading level is defined as whether the communication is below the eighth grade reading level unless it is obvious that an incoming request from the beneficiary contains language written at a higher level. In these cases, the appropriate reading level is tailored to the capacities and circumstances of the intended recipient.

In addition to evaluating performance based upon our expectations for FY 2009, we may also conduct follow-up evaluations throughout FY 2009 of areas in which contractor performance was out of compliance with statute, regulations, and our performance expectations during prior review years where contractors were required to submit a Performance Improvement Plan (PIP).

We may also utilize Statement of Auditing Standards-70 (SAS–70) reviews as a means to evaluate contractors in some or all business functions.

In FY 2001, we established the Contractor Rebuttal Process as a commitment to continual improvement of contractor performance evaluation (CPE). We will continue the use of this process in FY 2009. The Contractor Rebuttal Process provides the contractors an opportunity to submit a written rebuttal of CPE findings of fact. Whenever we conduct an evaluation of contractor operations, contractors have 7 calendar days from the date of the CPE review exit conference to submit a written rebuttal. The CPE review team or, if appropriate, the individual reviewer considers the contents of the rebuttal before the issuance of the final CPE report to the contractor.

The FY 2009 CPE for FIs and carriers is structured into five criteria designed to meet the stated objectives. The first criterion, claims processing, measures contractual performance against claims processing accuracy and timeliness requirements, as well as activities in handling appeals. Within the claims processing criterion, we have identified those performance standards that are mandated by legislation, regulation, or judicial decision. These standards include claims processing timeliness, the accuracy of Medicare Summary Notices (MSNs), the timeliness of FI and carrier redeterminations, and the appropriateness of the reading level and content of FI and carrier redetermination letters. Further evaluation in the claims processing criterion may include, but is not limited to, the accuracy of claims processing, the percent of claims paid with interest, the accuracy of redeterminations, timeliness of forwarding case files to and effectuation of Qualified Independent Contractor (QIC) decisions, and effectuation of administrative law judge (ALJ) decisions.

The second criterion, customer service, assesses the adequacy of the service provided to customers by the contractor in its administration of the Medicare program. Functions that may be evaluated under this criterion include, but will not be limited to, the following: (1) Timeliness and accuracy of all correspondence to providers; (2) monitoring the quality of replies provided by the contractor's provider telephone customer service representatives (quality call monitoring); and (3) provider outreach and education activities.

The third criterion, payment safeguards, evaluates whether the Medicare Trust Fund is safeguarded against inappropriate program expenditures. Intermediary and carrier performance may be evaluated in the areas of Medical Review (MR), Medicare Secondary Payer (MSP), Overpayments (OP), and Provider Enrollment (PE). In addition, FIs performance may be evaluated in the area of Audit and Reimbursement (A&R).

In FY 1996, the Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), Medicare Integrity Program, giving us the authority to contract with entities other than, but not excluding, Medicare carriers and intermediaries to perform certain program safeguard functions. In situations where one or more program safeguard functions are contracted to another entity, we may evaluate the flow of communication and information between a Medicare FFS contractor and the payment safeguard contractor. All benefit integrity functions have been transitioned from the intermediaries and carriers to the program safeguard contractors.

Mandated performance standards for FIs in the payment safeguards criterion include the accuracy of decisions on SNF demand bills and the timeliness of processing Tax Equity and Fiscal Responsibility Act (TEFRA) target rate adjustments, exceptions, and exemptions. There are no mandated performance standards for carriers in the payment safeguards criterion. FIs and carriers may also be evaluated on any Medicare Integrity Program (MIP) activities if performed under their agreement or contract.

The fourth criterion, fiscal responsibility, evaluates the contractor's efforts to protect the Medicare program and the public interest. Contractors must effectively manage Federal funds for both the payment of benefits and the costs of administration under the Medicare program. Proper financial and budgetary controls, including internal controls, must be in place to ensure

contractor compliance with its agreement with HHS and CMS.

Additional functions reviewed under this criterion may include, but are not limited to, adherence to approved budget, compliance with the Budget and Performance Requirements (BPRs), and compliance with financial reporting requirements.

The fifth and final criterion, administrative activities, measures a contractor's administrative management of the Medicare program. A contractor must efficiently and effectively manage its operations. Proper systems security (general and application controls), Automated Data Processing (ADP) maintenance, and disaster recovery plans must be in place. A contractor's evaluation under the administrative activities criterion may include, but is not limited to, establishment, application, documentation, and effectiveness of internal controls that are essential in all aspects of a contractor's operation, as well as the degree to which the contractor cooperates with us in complying with the Federal Managers' Financial Integrity Act of 1982 (FMFIA). Administrative activities evaluations may also include reviews related to contractor implementation of our general instructions and data and reporting requirements.

We have developed separate measures for RHHIs in order to evaluate the distinct RHHI functions. These functions include the processing of claims from freestanding HHAs, hospital-affiliated HHAs, and hospices. Through an evaluation using these criteria and standards, we may determine whether the RHHI is effectively and efficiently administering the program benefit or whether the functions should be moved from one FIs to another in order to gain that assurance.

In sections IV. through VI. of this notice, we list the criteria and standards to be used for evaluating the performance of FIs, RHHIs, and carriers.

IV. Criteria and Standards for Fiscal Intermediaries

A. Claims Processing Criterion

The claims processing criterion contains the following three mandated standards:

Standard 1. Not less than 95.0 percent of clean electronically submitted nonperiodic interim payment claims are paid within statutorily specified timeframes. Clean claims are defined as claims that do not require Medicare FIs to investigate or develop outside of their Medicare operations on a prepayment basis. Specifically, the Act specifies that clean nonperiodic interim payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt.

Standard 2. Redetermination letters prepared in response to beneficiary initiated appeal requests are written in a manner calculated to be understood by the beneficiary. Letters must contain the required elements as specified in § 405.956.

Standard 3. All redeterminations must be concluded and mailed within 60 days of receipt of the request, unless the party submits documentation after the request, in which case the decision-making timeframe is extended for up to 14 calendar days for each submission.

Because FIs process many claims for benefits under the Part B portion of the Medicare Program, we also may evaluate how well a FI follows the procedures for processing appeals of any claims for Part B benefits.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Accuracy of claims processing.
- Remittance advice transactions.
- Establishment and maintenance of a relationship with Common Working File (CWF) Host.
- Accuracy of redetermination decisions.
- QIC case file requirements.
- Timely and accurate effectuation of appeal decisions.
- Accuracy and timeliness of processing appeals and clerical error reopenings as set forth in part 405, subpart I (§ 405.900 *et seq.*).

B. Customer Service Criterion

Functions that may be evaluated under this criterion include, but are not limited to, the following:

- Maintaining a properly programmed interactive voice response system to assist with inquiries.
- Performing quality call monitoring.
- Training customer service representatives.
- Entering valid call center performance data in the customer service assessment and management system or its successor, the provider inquiry evaluation system.
- Providing timely and accurate written replies to providers that address the concerns raised and that are written with an appropriate customer-friendly tone and clarity.
- Ensuring written correspondence is evaluated for quality.
- Conducting provider outreach and education-activities.
- Effectively maintaining an Internet Web site dedicated to furnishing providers and physicians timely, accurate, and useful Medicare program information.

C. Payment Safeguards Criterion

The Payment Safeguard criterion contains the following two mandated standards:

Standard 1. Decisions on SNF demand bills are accurate.

Standard 2. TEFRA target rate adjustments, exceptions, and exemptions are processed within mandated timeframes. Specifically, applications must be processed to completion within 75 days after receipt by the contractor or returned to the hospitals as incomplete within 60 days of receipt.

FIs may also be evaluated on any MIP activities if performed under their Part A contractual agreement. *These functions and activities include, but are not limited to, the following:*

- Audit and Reimbursement

++ Performing the activities specified in our general instructions for conducting audit and settlement of Medicare cost reports.

++ Establishing accurate interim payments.

- Medical Review

++ Increasing the effectiveness of medical review activities.

++ Exercising accurate and defensible decision-making on medical reviews.

++ Collaborating with other internal components and external entities to ensure the effectiveness of medical review activities.

- Medicare Secondary Payer

++ Accurately following MSP claim development and edit procedures.

++ Auditing hospital files and claims to determine that claims are being filed to Medicare appropriately.

++ Supporting the Coordination of Benefits Contractor's efforts to identify responsible payers primary to Medicare.

++ Supporting the MSP Recovery functions for provider, physician or other supplier debts and duplicate provider, physician or other supplier payments.

++ Accurately reporting MSP savings.

- Overpayments

++ Collecting and referring Medicare debts in a timely manner.

++ Accurately reporting and collecting overpayments.

++ Adhering to our instructions for management of Medicare Trust Fund debts.

- Provider Enrollment

++ Complying with assignment of staff to the provider enrollment function and training the staff in procedures and verification techniques.

++ Complying with the operational standards relevant to the process for enrolling providers.

D. Fiscal Responsibility Criterion

We may review the FI's efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their agreements with us.

Additional functions that may be reviewed under the fiscal responsibility criterion include, but are not limited to, the following:

- Adherence to approved program management and MIP budgets.
- Compliance with the BPRs.
- Compliance with financial reporting requirements.
- Control of administrative cost and benefit payments.

E. Administrative Activities Criterion

We may measure an FI's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives.

We may measure an FI's efficiency and effectiveness in managing its operations. Proper systems security (general and application controls), ADP maintenance, and disaster recovery plans must be in place. A FI must also test system changes to ensure the accurate implementation of our instructions.

Our evaluation of FI under the administrative activities criterion may include, but is not limited to, reviews of the following:

- Systems security.
- ADP maintenance (configuration management, testing, change management, and security).
- Implementation of the Electronic Data Interchange (EDI) standards adopted for use under HIPAA.
- Disaster recovery plan and systems contingency plan.
- Data and reporting requirements implementation.
- Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.
- Implementation of our general instructions.

V. Criteria and Standards for Regional Home Health Intermediaries (RHHIs)

The following three standards are mandated for the RHHI criterion:

Standard 1. Not less than 95.0 percent of clean electronically submitted nonperiodic interim payment home health and hospice claims are paid within statutorily specified timeframes. Clean claims are defined as claims that do not require Medicare FIs to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, the statute specifies that clean non-periodic interim payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt.

Standard 2. Redetermination letters prepared in response to beneficiary initiated appeal requests are written in a manner calculated to be understood by the beneficiary. Letters must contain the required elements as specified in § 405.956.

Standard 3. All redeterminations must be concluded and mailed within 60 days of receipt of the request, unless the party submits documentation after the request, in which case the decision-making timeframe is extended for up to 14 calendar days for each submission.

We may use this criterion to review an RHHI's performance for handling the HHA and hospice workload. This includes processing HHA and hospice claims timely and accurately, properly paying and settling HHA cost reports, and accurately processing redeterminations of initial determinations from beneficiaries, HHAs, and hospices.

VI. Criteria and Standards for Carriers

A. Claims Processing Criterion

The claims processing criterion contains the following four mandated standards:

Standard 1. Not less than 95.0 percent of clean electronically submitted claims are processed within statutorily specified timeframes. Clean claims are defined as claims that do not require Medicare carriers to investigate or develop outside of their Medicare operations on a prepayment basis. Specifically, the Act specifies that clean non-periodic interim payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt.

Standard 2. Ninety-eight percent of MSNs are properly generated. Our expectation is that MSN messages are accurately reflecting the services provided.

Standard 3. Redetermination letters prepared in response to beneficiary initiated appeal requests are written in a manner calculated to be understood by the beneficiary. Letters must contain the required elements as specified in § 405.956.

Standard 4. All redeterminations must be concluded and mailed within 60 days of receipt of the request, unless the party submits documentation after the request, in which case the decision-making timeframe is extended for up to 14 calendar days for each submission.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Accuracy of claims processing.
- Remittance advice transactions.
- Establishment and maintenance of relationship with Common Working File (CWF) Host.
- Accuracy of redetermination decisions.
- QIC case file requirements.
- Timely and accurate effectuation of appeal decisions.
- Accuracy and timeliness of processing appeals and clerical error reopenings as set forth in part 405, subpart I (§ 405.900 *et seq.*).

B. Customer Service Criterion

Contractors must meet our performance expectations that providers are served by prompt and accurate administration of the program in accordance with all applicable laws, regulations, and our general instructions.

Functions that may be evaluated under this criterion include, but are not limited to, the following:

- Maintaining a properly programmed interactive voice response system to assist with inquiries.
- Performing quality call monitoring.
- Training customer service representatives.
- Entering valid call center performance data in the customer service assessment and management system or its successor the provider inquiry evaluation system.
- Providing timely and accurate written replies to providers that address the concerns raised and that are written with an appropriate customer-friendly tone and clarity.
- Ensuring written correspondence is evaluated for quality.
- Conducting provider outreach and education, activities.
- Effectively maintaining an Internet Web site dedicated to furnishing providers timely, accurate, and useful Medicare program information.

C. Payment Safeguards Criterion

Carriers may be evaluated on any MIP activities if performed under their contracts. *In addition, other carrier*

functions and activities that may be reviewed under this criterion include, but are not limited to the following:

• Medical Review

++ Increasing the effectiveness of medical review activities.

++ Exercising accurate and defensible decision-making on medical reviews.

++ Collaborating with other internal components and external entities to ensure the effectiveness of medical review activities.

• Medicare Secondary Payer

++ Accurately following MSP claim development/edit procedures.

++ Supporting the Coordination of Benefits Contractor's efforts to identify responsible payers primary to Medicare.

++ Supporting the Medicare Secondary Payer Recovery functions for provider, physician or other supplier debts and duplicate provider, physician or other supplier payments.

++ Accurately reporting MSP savings.

• Overpayments

++ Collecting and referring Medicare debts in a timely manner.

++ Accurately reporting and collecting overpayments.

++ Compliance with our instructions for management of Medicare Trust Fund debts.

• Provider Enrollment

++ Complying with assignment of staff to the provider enrollment function and training staff in procedures and verification techniques.

++ Complying with the operational standards relevant to the process for enrolling suppliers.

D. Fiscal Responsibility Criterion

We may review the carrier's efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their contracts.

Additional functions that may be reviewed under the Fiscal Responsibility criterion include, but are not limited to, the following:

• Adherence to approved program management and MIP budgets.

• Compliance with the BPRs.

• Compliance with financial reporting requirements.

• Control of administrative cost and benefit payments.

E. Administrative Activities Criterion

We may measure a carrier's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives.

We may measure a carrier's efficiency and effectiveness in managing its operations. Proper systems security (general and application controls), ADP maintenance, and disaster recovery plans must be in place. Also, a carrier must test system changes to ensure accurate implementation of our instructions.

Our evaluation of a carrier under this criterion may include, but is not limited to, reviews of the following:

• Systems security.

• ADP maintenance (configuration management, testing, change management, and security).

• Disaster recovery plan/systems contingency plan.

• Data and reporting requirements implementation.

• Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

• Implementation of the Electronic Data Interchange (EDI) standards adopted for use under the HIPAA.

• Implementation of our general instructions.

VII. Action Based on Performance Evaluations

We evaluate a contractor's performance against applicable program requirements for each criterion. Each contractor must certify that all information submitted to us relating to the contract management process, including, without limitation, all files, records, documents and data, whether in written, electronic, or other form, is accurate and complete to the best of the contractor's knowledge and belief. A contractor is required to certify that its files, records, documents, and data are not manipulated or falsified in an effort to receive a more favorable performance evaluation. A contractor must further certify that, to the best of its knowledge and belief, the contractor has submitted, without withholding any relevant information, all information required to be submitted for the contract management process under the authority of applicable law(s), regulation(s), contract(s), or our manual provision(s). Any contractor that makes a false, fictitious or fraudulent certification may be subject to criminal or civil prosecution, as well as appropriate administrative action. This administrative action may include debarment or suspension of the contractor, as well as the termination or nonrenewal of a contract.

If a contractor meets the level of performance required by operational instructions, it meets the requirements of that criterion. When we determine a contractor is not meeting performance requirements, we will use the terms ''major nonconformance'' or ''minor nonconformance'' to classify our findings. A major nonconformance is a nonconformance that is likely to result in failure of the supplies or services, or to materially reduce the usability of the supplies or services for their intended purpose. A minor nonconformance is a nonconformance that is not likely to materially reduce the usability of the supplies or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the supplies or services. The contractor will be required to develop and implement PIPs for findings determined to be either a major or minor nonconformance. The contractor will be monitored to ensure effective and efficient compliance with the PIP, and to ensure improved performance when requirements are not met.

The results of performance evaluations and assessments under all criteria applying to FIs, carriers, and RHHIs will be used for contract management activities and will be published in the contractor's annual Report of Contractor Performance (RCP). We may initiate administrative actions as a result of the evaluation of contractor performance based on these performance criteria. Under sections 1816 and 1842 of the Act, we consider the results of the evaluation in our determinations when—

• Entering into, renewing, or terminating agreements or contracts with contractors; and

• Deciding other contract actions for intermediaries and carriers (such as deletion of an automatic renewal clause). These decisions are made on a case-by-case basis and depend primarily on the nature and degree of performance. *More specifically, these decisions depend on the following:*

++ Relative overall performance compared to other contractors.

++ Number of criteria in which nonconformance occurs.

++ Extent of each nonconformance.

++ Relative significance of the requirement for which nonconformance occurs within the overall evaluation program.

++ Efforts to improve program quality, service, and efficiency.

++ Deciding the assignment or reassignment of providers and designation of regional or national intermediaries for classes of providers.

We make individual contract action decisions after considering these factors in terms of their relative significance

and impact on the effective and efficient administration of the Medicare program.

In addition, if the cost incurred by the FI, RHHI, or carrier to meet its contractual requirements exceeds the amount that we find to be reasonable and adequate to meet the cost that must be incurred by an efficiently and economically operated FIs or carrier, these high costs may also be grounds for adverse action.

VIII. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently the Office of Management and Budget need not review it under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IX. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable 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 notice, and, if we proceed with a subsequent document, we will respond to the comments in the section entitled as ''Analysis of and Response to Public Comments Received on FY 2009 Criteria and Standards'' of that document.

Authority: Sections 1816(f), 1834(a)(12), and 1842(b) of the Social Security Act (42 U.S.C. 1395h(f), 1395m(a)(12), and 1395u(b)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 16, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–14641 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3201–N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—August 20, 2008

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) (''Committee'') will be held on Wednesday, August 20, 2008. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. This meeting will focus on the oncologic indications of 2-[F–18] Fluoro-D-Glucose (FDG) positron emission tomography (PET) for nine cancers (brain, cervical, small cell lung, ovarian, pancreatic, testicular, prostate, bladder, and kidney). The panel will review the scientific evidence of the impact of PET as part of a management strategy to improve patient-centered outcomes. The panel will also consider data generated under a current national coverage determination that provides coverage for PET for specified cancers when additional data are prospectively collected. The meeting will discuss the various kinds of evidence that are useful to support requests for Medicare coverage in this field. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: *Meeting Date:* The public meeting will be held 7:30 a.m. until 4:30 p.m., d.s.t. on Wednesday, August 20, 2008.

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m., d.s.t. on July 21, 2008. Once submitted, comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker, and to submit Powerpoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., d.s.t. on Monday, July 21, 2008. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m., d.s.t. on Wednesday, August 13, 2008.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., d.s.t. Friday, August 8, 2008.

ADDRESSES:

Meeting Location: The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to *MedCACpresentations@cms.hhs.gov* or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for MedCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410–786–0309) or via e-mail at *Maria.Ellis@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

MedCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), provides advice and recommendations to CMS regarding clinical issues. (For more information on MCAC, see the December 14, 1998 **Federal Register** (63 FR 68780).) This notice announces the August 20, 2008, public meeting of the Committee. During this meeting, the Committee will review the scientific evidence of the impact of PET as part of a management strategy to improve patient-centered outcomes. The Committee will focus on evidence regarding the use of FDG PET to inform the treating physician on cancer diagnosis, staging, detecting metastatic disease and detecting recurrence. Background information about this topic, including panel materials, will become available at *http://www.cms.hhs.gov/coverage.*

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 30 minutes. The Committee may limit the number and duration of oral presentations to the

time available. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: *http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac*.

We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating the meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 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: June 17, 2008.

Barry M. Straube,

Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. E8–14649 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1394–N]

Medicare Program; Second Semi-Annual Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—August 27–29, 2008

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 2), this notice announces the second semi-annual meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel) for 2008. The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the APC groups and their associated weights. We will consider the Panel's advice as we prepare the final rule that updates the hospital Outpatient Prospective Payment System (OPPS) for CY 2009.

DATES: *Meeting Dates:* We are scheduling the second semi-annual meeting in 2008 for the following dates and times:

- Wednesday, August 27, 2008, 1 p.m. to 5 p.m. (e.d.t.) [1]
- Thursday, August 28, 2008, 8 a.m. to 5 p.m. (e.d.t.) [1]
- Friday, August 29, 2008, 8 a.m. to 12 noon (e.d.t.) [2]

Deadlines

Deadline for Hardcopy Comments/Suggested Agenda Topics

5 p.m. (e.d.t.), Monday, August 4, 2008.

Deadline for Hardcopy Presentations

5 p.m. (e.d.t.), Monday, August 4, 2008.

Deadline for Attendance Registration

5 p.m. (e.d.t.), Wednesday, August 13, 2008.

Deadline for Special Accommodations

5 p.m. (e.d.t.), Wednesday, August 13, 2008.

Submission of Materials to the Designated Federal Officer (DFO): Because of staffing and resource limitations, we cannot accept written comments and presentations by FAX, nor can we print written comments and presentations received electronically for dissemination at the meeting.

Only hardcopy comments and presentations can be reproduced for public dissemination. All hardcopy presentations *must be accompanied by Form CMS–20017 (revised 01/07).* The form is now available through the CMS Forms Web site. The Uniform Resource Locator (URL) for linking to this form is as follows: *http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf.*

Presenters must use the most recent copy of CMS–20017 (updated 01/07) at the above URL. Additionally, presenters must *clearly* explain the action(s) that they are requesting CMS to take in the appropriate section of the form. They must also clarify their relationship to the organization that they represent in the presentation.

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[1] The times listed in this notice are approximate times; consequently, the meetings may last longer than listed in this notice—but will not begin before the posted times.

[2] If the business of the Panel concludes on Thursday, August 28, 2008, there will be no Friday (August 29, 2008) meeting.

Note: Issues that are vague, or that are outside the scope of the APC Panel's purpose, will not be considered for presentations and comments. There will be no exceptions to this rule. We appreciate your cooperation on this matter.

We are also requiring electronic versions of the written comments and presentations, in addition to the hardcopies, to be sent electronically to the Panel members for their review before the meeting.

In summary, presenters and/or commenters must do the following:

- Send both electronic and hardcopy versions of their presentations and written comments by the prescribed deadlines.
- Send electronic transmissions to the e-mail address below.
- Do not send pictures of patients in any of the documents unless their faces have been blocked out.
- Do not send documents electronically that have been archived.
- Mail (or send by courier) to the DFO all hardcopies, accompanied by Form CMS–20017 (revised 01/07), if they are presenting, as specified in the **FURTHER INFORMATION CONTACT** section of this notice.
- Commenters are not required to send Form CMS–20017 with their written comments.

ADDRESSES: The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: Shirl Ackerman-Ross, DFO, CMS, CMM, HAPG, DOC, 7500 Security Boulevard, Mail Stop C4–05–17, Baltimore, MD 21244–1850. *Phone:* (410) 786–4474.

Note: We recommend that you advise couriers of the following information: When delivering hardcopies of presentations to CMS, if no one answers at the above phone number, call (410) 786–4532 or (410) 786–9316.) E-mail address for comments, presentations, and registration requests is *CMS APCPanel@cms.hhs.gov.*

Note: There is NO underscore in this e-mail address; there is a SPACE between CMS and APCPanel.

News media representatives must contact our Public Affairs Office at (202) 690–6145.

Advisory Committees' Information Lines: The phone numbers for the CMS Federal Advisory Committee Hotline are 1–877–449–5659 (toll free) and (410) 786–9379 (local).

Web Sites: The following information is available on the CMS Web site at *http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.*

Note: There is an UNDERSCORE after FACA/05(like this_); there is no space.

- Additional information on the APC meeting agenda topics.
- Updates to the Panel's activities.
- Copies of the current Charter.
- Membership requirements.

You may also search information about the APC Panel and its membership in the FACA database at the following URL: *https://www.fido.gov/facadatabase/public.asp.*

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary is required by section 1833(t)(9)(A) of the Social Security Act (the Act), as amended by section 201(h) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), and re-designated by section 202(a)(2) of the BBRA to establish and consult with an expert outside advisory panel regarding the clinical integrity of the APC groups and weights that are components of the hospital OPPS.

The APC Panel meets up to three times annually. The Charter requires that the Panel must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. The Panel consists of up to 15 members who are representatives of providers and a Chair.

Each Panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS. All Panel members must have technical expertise that enables them to participate fully in the work of the Panel. The expertise encompasses hospital payment systems, hospital medical-care delivery systems, provider billing systems, outpatient payment requirements, APC groups, Current Procedural Terminology codes, and the use and payment of drugs and medical devices in the outpatient setting, as well as other forms of relevant expertise. Details regarding membership requirements for the APC Panel are found on the FACA and CMS Web sites as listed above.

The Panel presently consists of the following members:

- E.L. Hambrick, M.D., J.D., Chair.
- Gloryanne Bryant, B.S., R.H.I.A., R.H.I.T., C.C.S.
- Patrick Grusenmeyer, Sc.D.
- Hazel Kimmel, R.N., C.C.S., C.P.C.
- Michael Mills, Ph.D.
- Thomas Munger, M.D.
- Agatha Nolen, D.Ph., M.S.
- Beverly Khnie Philip, M.D.
- Louis Potters, M.D., F.A.C.R.
- Russ Ranallo, M.S.
- James V. Rawson, M.D.
- Michael Ross, M.D.
- Judie S. Snipes, R.N., M.B.A., F.A.C.H.E.
- Patricia Spencer-Cisek, M.S., APRN–BC, AOCN®
- Kim Allan Williams, M.D., F.A.C.C., F.A.B.C.
- Robert M. Zwolak, M.D., Ph.D. F.A.C.S.

II. Agenda

The agenda for the August 2008 meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Reconfiguring APCs (for example, splitting of APCs, moving Healthcare Common Procedure Coding System (HCPCS) codes from one APC to another and moving HCPCS codes from new technology APCs to clinical APCs).
- Evaluating APC weights.
- Packaging device and drug costs into APCs: Methodology, effect on APCs, and need for reconfiguring APCs based upon device and drug packaging.
- Removing procedures from the inpatient list for payment under the OPPS.
- Using single and multiple procedure claims data.
- Addressing other APC structure technical issues.

Note: The subject matter before the Panel will be limited to these and related topics. Issues related to calculation of the OPPS conversion factor, charge compression, pass-through payments, or wage adjustments are not within the scope of the Panel's purpose. Therefore, these issues will not be considered for presentations and/or comments. There will be no exceptions to this rule. We appreciate your cooperation on this matter.

The Panel may use data collected or developed by entities and organizations, other than DHHS and CMS, in conducting its review. We recommend organizations to submit data for the Panel's and CMS staff's review.

III. Written Comments and Suggested Agenda Topics

Send hardcopy and electronic written comments and suggested agenda topics to the DFO at the address indicated above. The DFO must receive these items by 5 p.m. (e.d.t.), Monday, August 4, 2008. There will be no exceptions. We appreciate your cooperation on this matter.

The written comments and suggested agenda topics submitted for the August 2008 APC Panel meeting must fall within the subject categories outlined in the Panel's Charter and as listed in the Agenda section of this notice.

IV. Oral Presentations

Individuals or organizations wishing to make 5-minute oral presentations must submit hardcopy and electronic versions of their presentations to the

DFO by 5 p.m. (e.d.t.), Monday, August 4, 2008, for consideration.

The number of oral presentations may be limited by the time available. Oral presentations should not exceed 5 minutes in length for an individual or an organization.

The Chair may further limit time allowed for presentations due to the number of oral presentations, if necessary.

V. Presenter and Presentation Information

All presenters must submit Form CMS–20017 (revised 01/07). Hardcopies are required for oral presentations; however, electronic submissions of Form CMS–20017 are optional. The DFO must receive the following information from those wishing to make oral presentations:

- Form CMS–20017 completed with all pertinent information identified on the first page of the presentation.
- One hardcopy of presentation.
- Electronic copy of presentation.
- Personal registration information as described in the Meeting Attendance section below.
- Those persons wishing to submit comments only must send hardcopy and electronic versions of their comments, but they are not required to submit Form CMS–20017.

VI. Oral Comments

In addition to formal oral presentations, there will be opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

VII. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Attendance will be determined on a first-come, first-served basis.

Persons wishing to attend this meeting, which is located on Federal property, must e-mail the DFO to register in advance no later than 5 p.m. (e.d.t.), Wednesday, August 13, 2008. A confirmation will be sent to the requester(s) by return e-mail.

The following personal information must be e-mailed to the DFO by the date and time above:

- Name(s) of attendee(s);
- Title(s);
- Organization;
- E-mail address(es); and
- Telephone number(s).

VIII. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on Wednesday, August 13, 2008. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors will be held 30 to 45 minutes before the meeting start time each day. You should allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 12:15 p.m. for the 1 p.m. meeting on Wednesday, August 27, 2008. Plan to arrive at the building by 7:15 a.m. on Thursday, August 28, 2008 (and Friday, August 29, 2008—if we have a meeting that day) to ensure that you are able to arrive promptly at the meeting by 8 a.m. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, including personal items such as desktops, cell phones, and palm pilots, are subject to physical inspection.

The following are the security, building, and parking guidelines:

- Persons attending the meeting including presenters must be registered and on the attendance list by the prescribed date.
- Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.
- Attendees must present photographic identification to the Federal Protective Service or Guard Service personnel before entering the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.

IX. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must send a request for these services to the DFO by 5 p.m. (e.d.t.), Wednesday, August 13, 2008.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 16, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–13828 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0154]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 28, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0119. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Good Laboratory Practice (GLP) Regulations for Nonclinical Studies—21 CFR Part 58 (OMB Control Number 0910–0119)—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360(b), 360(e)) and related statues require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the agency issued the GLP regulations. The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

The GLP regulations contain requirements for the reporting of the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also contain recordkeeping requirements relating to the conduct of safety studies. Such records include the following information: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

The information collected under GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by persons desiring to market new products. The facilities that collect this information are typically operated by large entities, e.g., contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies. Failure to include the information in a filing to FDA would mean that agency scientific experts could not make a valid determination of product safety. FDA receives, reviews, and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts onsite audits of records and reports, during its inspections of testing laboratories, to verify reliability of results submitted in applications.

The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies.

In the **Federal Register** of March 12, 2008 (73 FR 13240), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
58.35(b)(7)	300	60.25	18,075	1	18,075
58.185	300	60.25	18,075	27.65	499,774
Total					517,849

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
58.29(b)	300	20	6,000	.21	1,260
58.35(b)(1) through (b)(6) and (c)	300	270.76	81,228	3.36	272,926
58.63(b) and (c)	300	60	18,000	.09	1,620
58.81(a) through (c)	300	301.8	90,540	.14	12,676
58.90(c) and (g)	300	62.7	18,810	.13	2,445
58.105(a) and (b)	300	5	1,500	11.8	17,700
58.107(d)	300	1	300	4.25	1,275
58.113(a)	300	15.33	4,599	6.8	31,273
58.120	300	15.38	4,614	32.7	150,878
58.195	300	251.5	75,450	3.9	294,255
Total					786,308

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 20, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14535 Filed 6–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0172]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 28, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0117. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drugs for Investigational Use (OMB Control Number 0910–0117)—Extension

FDA has authority under the Federal Food, Drug, and Cosmetic Act (the act) to approve new animal drugs. Section 512(j) of the act (21 U.S.C.360b(j)), authorized FDA to issue regulations for the investigational use of new animal drugs. The regulations which set forth conditions for investigational use of new animal drugs are codified under part 511 (21 CFR part 511). If a new animal drug is only for tests in vitro, or testing in laboratory research animals, the person distributing the new animal drug must maintain records showing: (1) The name and post office address of the expert or expert organization to whom the drug is shipped; and (2) the date, quantity, batch or code mark for each shipment for a period of 2 years after such shipment or delivery. Prior to shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). The NCIE must contain, among other things, the following specific information: (1) The identity of the new animal drug, (2) labeling, (3) a statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) the name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe and that the distribution is controlled to prevent potential abuse. The agency uses these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by the pharmaceutical industry, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical professional. Respondents to this collection of information are investigators who use new animal drugs for investigational purposes.

In the **Federal Register** of April 8, 2008 (73 FR 19073), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(4)	134	7.66	1027	8	8,216
511.1(b)(5)	134	.19	25	140	3,500
511.1(b)(6)	134	.01	2	1	2
511.1(b)(8) (ii)	134	.11	15	20	300
511.1(b)(9)	134	6.7	20	8	160
Total					12,178

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(a)(3)	134	2.96	400	9	3,600
511.1(b)(3)	134	7.66	1,027	1	1,027

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(b)(7)(ii)	134	7.46	1,000	3.5	3,500
511.1(b)(8)(i)	134	7.46	1,000	3.5	3,500
Total					11,627

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates for reporting requirements, record preparation, and maintenance for this collection of information are based on agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 134 respondents. We use this estimate consistently throughout the table and calculated the ''annual frequency per respondent'' by dividing the total annual responses by number of respondents. Additional information needed to make final calculations of the total burden hours i.e., the number of respondents, the number of record keepers, the number of NCIEs received, etc., was derived from agency records.

Dated: June 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14653 Filed 6–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0227]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 28, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0485. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Labeling Regulations—(OMB Control Number 0910–0485)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to a regulatory action. Certain provisions under section 502 of the act require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices, on the labels or labeling for the devices. Section 502(b) of the act requires that for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor as well as an accurate statement of the quantity of the contents. Section 502(f) of the act requires that the labeling for a device must contain adequate directions for use. FDA may however, grant an exemption, if the agency determines that the adequate directions for use labeling requirements are not necessary for the particular case, as it relates to protection of the public health.

FDA regulations under parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves or the devices, on the label or labeling for the devices to health professionals and consumers. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations under parts 800, 801, and 809 are derived from requirements of section 502 of the act, which provides in part, that a device shall be misbranded if among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use.

Reporting Burden

Sections 800.10(a)(3) and 800.12(c) require that the label for contact lens cleaning solutions bear a prominent statement alerting consumers of the tamper-resistant feature. Further, § 800.12 requires that packaged contact lens cleaning solutions contain a tamper-resistant feature, to prevent malicious adulteration.

Section 800.10(b)(2) requires that the labeling for liquid ophthalmic preparations packed in multiple-dose containers provide information on the duration of use and the necessary warning information to afford adequate protection from contamination during use.

Section 801.1 requires that the label for a device in package form, contain the name and place of business of the manufacturer, packer, or distributor.

Section 801.5 requires that labeling for a device include information on intended use as defined under § 801.4 and provide adequate directions to assure safe use by the lay consumers.

Section 801.61 requires that the principal display panel of an over-the-counter (OTC) device in package form must bear a statement of the identity of the device. The statement of identity of the device must include the common name of the device followed by an accurate statement of the principal intended actions of the device.

Section 801.62 requires that the label for an OTC device in package form, must bear a statement of declaration of the net quantity of contents. The label

must express the net quantity in terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size.

Section 801.109 establishes labeling requirements for prescription devices, in which the label for the device must describe the application or use of the device, and contain a cautionary statement restricting the device for sale by, or on the order of an appropriate professional.

For prescription by a licensed practitioner, § 801.110 establishes labeling requirements for a prescription device delivered to the ultimate purchaser or user.

The device must be accompanied by labeling bearing the name and address of the licensed practitioner, directions for use, and cautionary statements if any, provided by the order.

Section 801.150(e) requires a written agreement between firms involved when a non-sterile device is assembled or packaged with labeling that identifies the final finished device as sterile, for which the device is ultimately introduced into interstate commerce to an establishment or contract manufacturer to be sterilized. When a written agreement complies with the requirements under § 801.150(e), FDA takes no regulatory action against the device as being misbranded or adulterated. In addition, § 801.150(e) requires that each pallet, carton, or other designated unit, be conspicuously marked to show its non-sterile nature when introduced into interstate commerce, and while being held prior to sterilization.

Section 801.405(b)(1) provides for labeling requirements for articles, including repair kits, re-liners, pads, and cushions, intended for use in temporary repairs and refitting of dentures for lay persons. Section 801.405(b)(1) also requires that the labeling contain the word ''emergency'' preceding and modifying each indication-for-use statement for denture repair kits and the word ''temporary'' preceding and modifying each indication-for-use statement for re-liners, pads, and cushions.

Section 801.405(c) provides for labeling requirements that contain essentially the same information described under § 801.405(b)(1). The information is intended to enable a lay person to understand the limitations of using OTC denture repair kits, and denture re-liners, pads, and cushions.

Section 801.420(c)(1) requires that manufacturers or distributors of hearing aids develop a user instructional brochure to be provided by the dispenser of the hearing aid to prospective users. The brochure must contain detailed information on the use and maintenance of the hearing aid.

Section 801.420(c)(4) establishes requirements that the user instructional brochure or separate labeling, provide for technical data elements useful for selecting, fitting, and checking the performance of a hearing aid. In addition, § 801.420(c)(4) provides for testing requirements to determine that the required data elements must be conducted in accordance with the American National Standards Institute's (ANSI) ''Specification of Hearing Aid Characteristics,'' ANSI S3.22–1996 (ASA 70–1996); (Revision of ANSI S3.22–1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Section 801.421(b) establishes requirement for the hearing aid dispenser to provide prospective users with a copy of the user instructional brochure along with an opportunity to review comments, either orally or by the predominant method of communication used during the sale.

Section 801.421(c) establishes requirements for the hearing aid dispenser to provide a copy of the user instructional brochure to the prospective purchaser of any hearing aid upon request or, if the brochure is unavailable, provide the name and address of the manufacturer or distributor from which it may be obtained.

Section 801.430(d) establishes labeling requirements for menstrual tampons to provide information on signs, risk factors, and ways to reduce the risk of Toxic Shock Syndrome (TSS).

Section 801.430(e)(2) requires menstrual tampon package labels to provide information on the absorbency term based on testing required under § 801.430(f) and an explanation of selecting absorbencies that reduce the risk of contracting TSS.

Section 801.430(f) establishes requirements that manufacturers of menstrual tampons devise and follow an ongoing sampling plan for measuring the absorbency of menstrual tampons. Further, manufacturers must use the method and testing parameters described under this section.

Section 801.435(b), (c), and (h), establishes requirements for condom labeling to bear an expiration date that is supported by testing that demonstrates the integrity of three random lots of the product.

Section 809.10(a) and (b) establishes requirements that a label for an in vitro diagnostic device and the accompanying labeling (package insert), must contain information identifying its intended use, instructions for use and lot or control number, and source.

Section 809.10(d)(1) provides that the labeling requirements for general purpose laboratory reagents may be exempt from the requirements of § 809.10(a) and (b), if the labeling contains information identifying its intended use, instructions for use, lot or control number, and source.

Section 809.10(e) provides that the labeling for ''Analytic Specific Reagents'' (ASRs) must provide information identifying the quantity or proportion or each reagent ingredient, instructions for use, lot or control number, and source.

Section 809.10(f) provides that, the labeling for OTC test sample collection systems for drugs of abuse must include information on the intended use, specimen collection instructions, identification system, and information about use of the test results. In addition, § 809.10(f) requires that this information be in a language appropriate for the intended users.

Section 809.30(d) requires that advertising and promotional materials for ASRs include the identity and purity of the ASR and the identity of the analyte.

Recordkeeping Burden

Section 801.150(a)(2) establishes recordkeeping requirements for re-processors, re-labelers, or re-packagers to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for 2 years after the shipment or delivery of the device. Section 801.150(a)(2) also requires that the subject respondents make copies of this agreement available for inspection at any reasonable hour to any officer or employee of the Department of Health and Human Services (DHHS), upon their request.

Section 801.421(d) establishes requirements for hearing aid dispensers to retain copies of all physician statements or any waivers of medical evaluation for 3 years after dispensing the hearing aid.

Section 801.410(e) requires copies of invoices, shipping documents, and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, be maintained for 3 years by the retailer and made available upon request by any officer or employee of the FDA or by any other officer or employee acting on behalf of the Secretary of Health and Human Services.

Section 801.410(f) requires that the results of impact tests and description of

the test method and apparatus be retained for a period of 3 years.

Section 801.421(d) requires hearing aid dispensers to retain a copy of any written statement from a physician required under § 801.421(a)(1), or any written statement waiving medical evaluation required under § 801.421(a)(2)(iii) for 3 years after the dispensing the hearing aid.

Section 801.435(g) requires latex condom manufacturers to document and provide, upon request, an appropriate justification for the application of the testing data from one product on any variation of that product to support expiration dating in the user labeling.

In the **Federal Register** of April 23, 2008 (73 FR 21959), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.10(a)(3) and 800.12(c)	4	10	40	1	40
800.10(b)(2)	4	10	40	40	1,600
801.1	30,000	3.5	105,000	0.1	10,500
801.5	5,000	3.5	17,500	22.35	391,125
801.61	5,000	3.5	17,500	1	17,500
801.62	1,000	5	5,000	1	5,000
801.109	18,000	3.5	63,000	17.77	1,119,510
801.110	10,000	50	500,000	0.25	125,000
801.150(e)	2	1	2	0.50	1
801.405(b)(1) and (c)	40	1	40	4	160
801.420(c)(1)	275	5	1,375	40	55,000
801.420(c)(4)	275	5	1,375	80	110,000
801.421(b)	10,000	160	1,600,000	0.30	480,000
801.421(c)	10,000	5	50,000	0.17	8,500
801.430(d) and (e)(2)	8	5	40	2	80
801.430(f)	8	5	40	80	3,200
801.435(b), (c), and (h)	135	1	135	96	12,960
809.10(a) and (b)	1,700	6	10,200	80	816,000
809.10(d)(1)	300	2	600	40	24,000
809.10(e)	300	25	7,500	1	7,500
809.10(f)	20	1	20	100	2,000
809.30(d)	300	25	7,500	1	7,500
Total					3,197,416

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
801.150(a)(2)	57	1	57	0.50	28
801.410(e) and (f)	30	924,100	27,723,000	.0008	22,178
801.421(d)	10,000	160	1,600,000	0.25	400,000
801.435(g)	4	3	12	40	480
Total Hours					422,686

[1]. There are no capital costs or operating and maintenance costs associated with this information collection.

This regulation also refers to previously approved collections of information found in FDA regulations. The collections of information under §§ 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231; and the collections of information under § 801.435(g) have been approved under OMB control number 0910–0073.

Further, FDA concludes that labeling statements under §§ 801.63; 801.405(b)(2) and (b)(3); 801.420(c)(2) and (c)(3); 801.430(c) and(e)(1); 801.433; 801.437(d) through (g); 809.30(d)(2), (d)(3), and (e) do not constitute a ''collection of information'' under the PRA. Rather, these labeling statements are ''public disclosure'' of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Reporting

These estimates are based on FDA's registration and listing database for medical device establishments, agency communications with industry, and FDA's knowledge of, and experience with device labeling.

Recordkeeping

These estimates are based on FDA's registration and listing database for medical device establishments, agency communications with industry, and FDA's knowledge of and experience with device labeling. In addition, the Vision Council of America provided the growth rate used to estimate the burden under § 801.410(e) and (f).

FDA is correcting its recordkeeping burden estimate for § 801.410(e) and (f). In the **Federal Register** of April 23, 2008, the recordkeeping burden estimate in Table 2 was overestimated as 11,935,028 hours. The corrected recordkeeping burden estimate for this proposed collection is 422,686 hours. The correction for the recordkeeping burden estimate was necessary due to two errors. First, FDA incorrectly gave an estimate of 0.25 hours per recordkeeper for § 801.410(e) and (f). The corrected estimate is 0.0008 hours per recordkeeper. Secondly, FDA inadvertently duplicated the recordkeeping burden for these sections.

This regulation also refers to previously approved collections of information found in FDA regulations. The collections of information under §§ 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; and the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231.

The information collection requirements under §§ 801.22, 801.63, 801.405(b)(2) and (b)(3), 801.420(c)(2) and (c)(3), 801.430(c) and (e)(1), 801.433, 801.437(d) through (g); 809.30(d)(2), (d)(3), and (e) are not considered information collection because the public information is originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

We have not estimated a burden for information that is disclosed to third parties, because it is a ''usual and customary'' part of a medical device manufacturer, distributor, or importer's normal business activities. Nor have we estimated a burden for time that is spent designing labels to improve the format or presentation.

Dated: June 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14658 Filed 6–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0168]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 28, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0303. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Records; Electronic Signatures—(OMB Control Number 0910–0303)—Extension

The FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures; (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

In the **Federal Register** of March 26, 2008 (73 FR 16017), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11.100	4,500	1	4,500	1	4,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
11.10	2,500	1	2,500	20	50,000
11.30	2,500	1	2,500	20	50,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					280,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14659 Filed 6–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Core Instrumentation.

Date: July 14–15, 2008.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph D. Mosca, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5158, MSC 7808, Bethesda, MD 20892, 301–435–2344, *moscajos@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Dermatology/Rheumatology Small Business, Special Emphasis Panel.

Date: July 18–22, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Daniel F. McDonald, PhD, Scientific Review Officer, Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cancer Biology.

Date: July 18, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Denise R. Shaw, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301–435–0198, *shawkath@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Discovery of Novel Epigenetic Marks.

Date: July 25, 2008.

Time: 8 a.m. to 9 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Richard Panniers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Sharing Data and Tools and Data Ontologies.

Date: July 28, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5144, MSC 7812, Bethesda, MD 20892, 301–435–2902, *gubina@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Drug Abuse Aspects of HIV/AIDS.

Date: July 28, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark P. Rubert, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Development of Assays for High Throughput Screening.

Date: July 30, 2008.

Time: 8 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: James J. Li, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301–435–2417, *lijames@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Electrochemistry, Spectroscopy, and Sensor Development Panel.

Date: August 5, 2008.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Vonda K. Smith, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7806, Bethesda, MD 20892, 301–435–1789, *smithvo@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 19, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–14600 Filed 6–26–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Conference Grant Review Committee.

Date: July 18, 2008.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Mark R. Green, PhD, Deputy Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1431, *mgreen1@nida.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: June 19, 2008

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–14599 Filed 6–26–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: 2009 National Survey on Drug Use and Health—(OMB No. 0930–0110)—Revision

The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

In the 2009 NSDUH, one scale measuring impairment from mental health issues will be adopted. The decision to adopt either the Sheehan or the WHO–DAS is currently being evaluated in the 2008 NSDUH by using the SCID–I/NP as a follow-up interview with a subsample of respondents. Based upon a substantive review of questions in the Youth Mental Health Services Utilization module, some additions and deletions will be made to this section to more specifically depict the types of providers and service delivery sites for youth mental health services. The remaining modular components of the questionnaire will remain essentially unchanged except for minor modifications to wording.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2009 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is shown below:

	No. of responses	Responses per respondent	Average burden per response (hr.)	Total burden (hrs)
Household Screening	190,800	1	.083	15,836

	No. of responses	Responses per respondent	Average burden per response (hr.)	Total burden (hrs)
Interview	67,500	1	1.0	67,500
Clinical Follow-up Certification	30	1	1.0	30
Clinical Follow-up Interview	500	1	1.0	500
Screening Verification	5,400	1	0.067	362
Interview Verification	10,125	1	0.067	678
	190,800			84,906

Written comments and recommendations concerning the proposed information collection should be sent by July 28, 2008 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: June 20, 2008.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. E8–14578 Filed 6–26–08; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2008–0049]

Science and Technology Directorate; Submission for Review; Information Collection Request for the DHS S&T Biodefense Knowledge Center Expert Database; Correction

AGENCY: Science and Technology Directorate, DHS.

ACTION: 30-day Notice and request for comment; Correction.

SUMMARY: The Department of Homeland Security (DHS) published a document in the **Federal Register** on May 22, 2008, concerning a 30-day notice and request for comment on the Biodefense Knowledge Center Expert Database. The document contained the incorrect name of the Biodefense Knowledge Center, incorrectly written as Bio-Knowledge Center, as well as incorrect information in the summary, supplementary information, and overview of the information collection portion of the notice.

FOR FURTHER INFORMATION CONTACT: Dave Shepherd, 202–254–5897.

Corrections

In the **Federal Register** of May 22, 2008, in FR Doc. E8–11454, on page 29773, in the second column, correct the **SUMMARY** caption to read: The Department of Homeland Security (DHS) invites the general public to comment on a new data collection form for the Biodefense Knowledge Center Expert Database: Subject Matter Expert (SME) Registration Form (DHS Form 10043). The Biodefense Knowledge Center Database will collect SME information in order to understand who can provide scientific expertise for peer review of classified life science programs. In addition, the directory will make it easier to identify scientific specialty areas for which there is a shortage of SMEs with appropriate security clearances. SME contact information, scientific expertise, and level of education will be collected electronically through a web portal currently being developed by DHS S&T. The SME information will be shared with U.S. Government program managers who have a legitimate need to identify life sciences SMEs. Cleared SMEs are necessary to accomplish scientific reviews and attend topical meetings. This notice and request for comments is required by the Paperwork Reduction Act of 1995 (Pub. Law 104–13, 44 U.S.C. chapter 35). Previously, a 60-day notice was published in the **Federal Register** on March 14, 2008.

In the **Federal Register** of May 22, 2008, in FR Doc. E8–11454, on page 29773, in the third column, correct the first sentence of the **SUPPLEMENTARY INFORMATION** caption to read: The National Counterproliferation Center has identified the need for a comprehensive and readily available list of life science SMEs who have security clearance status.

In the **Federal Register** of May 22, 2008, in FR Doc. E8–11454, on page 29774, in the first column, correct the last sentence of the third bullet under the ''*Overview of this Information Collection*'' caption to read: The SME information will be shared with U.S. Government program managers who have a legitimate need to identify life science SMEs.

Dated: June 16, 2008.

Kenneth D. Rogers,

Chief Information Officer, Science and Technology Directorate.

[FR Doc. E8–14643 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Science and Technology Directorate; Notice of Availability (NOA) for the Draft Environmental Impact Statement (DEIS) for the proposed National Bio and Agro-Defense Facility (NBAF)

AGENCY: Science and Technology Directorate (Office of National Laboratories within the Office of Research), DHS.

ACTION: Notice of Availability of the Draft Environmental Impact Statement for the National Bio and Agro-Defense Facility (NBAF).

SUMMARY: The Proposed Action to site, build, and construct the National Bio and Agro-Defense Facility (NBAF) would allow researchers to study foreign animal diseases (FAD) and zoonotic diseases (transmitted from animals to humans) for basic research, improving diagnostic tests, and developing effective vaccines and other countermeasures such as antiviral therapies. DHS anticipates that the NBAF would focus biosafety level 3 agricultural (BSL–3Ag) research on African swine fever, classical swine fever, contagious bovine pleuropneumonia, foot and mouth disease (FMD), Japanese encephalitis, and Rift Valley fever (RVF), as well as BSL–4 research on Hendra and Nipah viruses. The NBAF would be approximately 500,000 to 520,000 square feet and consist of a primary laboratory building with a vaccine development laboratory adjacent or contiguous to it. The primary research building would contain the BSL–2, BSL–3E, BSL–3Ag, and BSL–4 laboratories with their associated support spaces. The other laboratory building would be a current good manufacturing practice (cGMP) laboratory adjacent to the primary

research laboratory. The cGMP laboratory would be needed for vaccine candidate production. Other out buildings would be considered ancillary and necessary to support operation of the NBAF. Those buildings would include a guardhouse, transshipping facility, and central utility plant.

DATES: The comment period for the DEIS will end 60 days after publication of the NOA in the **Federal Register** by the U.S. Environmental Protection Agency.

ADDRESSES: To obtain a copy of the DEIS, ask questions, or submit written comments, contact Department of Homeland Security; Science and Technology Directorate; Mr. James V. Johnson: Mail Stop #2100; 245 Murray Lane, SW., Building 410; Washington, DC 20528.

FOR FURTHER INFORMATION CONTACT: All comments, both oral and written, received during this 60 day public comment period will be given equal consideration when finalizing the NBAF EIS. Comments may be submitted at the public meetings or online at *http://www.dhs.gov/nbaf* [click on Environmental Impact Statement]. You may also call: Toll-free fax 1–866–508–NBAF (6223); Toll-free voice mail; or 1–866–501–NBAF (6223).

SUPPLEMENTARY INFORMATION: Consultation between DHS and the United States Department of Agriculture (USDA) on a coordinated biodefense strategy called for in Homeland Security Presidential Directives 9 and 10 have revealed a gap that must be filled by an integrated research, development, test, and evaluation (RD&T) infrastructure for combating bio and agro terrorism threats. DHS S&T is responsible for filling this gap in a safe, secure, and environmentally sound manner. The proposed NBAF is envisioned to provide the nation with the first integrated agricultural zoonotic disease and animal health RD&T facility with the capability to address threats from high consequence zoonotic disease agents and foreign animal diseases.

DHS intends to select a single site for the construction of the NBAF. The NBAF DEIS analyzes six action alternatives as well as the No Action Alternative. The six action alternatives include construction and operation of the proposed NBAF at one of the following six site alternatives: (1) South Milledge Avenue Site; Athens, Georgia; (2) Manhattan Campus Site; Manhattan, Kansas; (3) Flora Industrial Park Site; Flora, Mississippi; (4) Plum Island Site; Plum Island, New York; (5) Umstead Research Farm Site; Butner, North Carolina; and (6) Texas Research Park Site; San Antonio, Texas. Under the No Action Alternative, the NBAF would not be constructed and DHS would continue to use the Plum Island Animal Disease Center with necessary investments in facility upgrades, replacements, and repairs so that it could continue to operate at its current capability, but not the expanded mission requirements associated with the NBAF.

DHS has not identified a Preferred Alternative. The evaluation conducted during the NEPA process will be used in conjunction with other factors to assist DHS in selecting the proposed federal action. Additional studies are being performed concurrently with this EIS that will provide important decision-making information. Results of these studies will be used in the development of the Final EIS and the Record of Decision (ROD). In order to make these decisions and formulate the ROD, the following reports will be considered: (1) EIS, (2) Threat and Risk Assessment, (3) Site Cost Analysis, (4) Site Characterization Study, (5) Plum Island Facility Closure and Transition Cost Study; and (6) Prior analysis of the alternative sites against DHS's site selection evaluation criteria.

The information contained in these reports will assist DHS and USDA, a major stakeholder in this endeavor, in considering the protection of the public and the environment while meeting the need for a modern, high-security BSL–3Ag and BSL–4 research facility with the capabilities needed to address potential threats to our agriculture.

Comments on the Draft EIS received during the 60-day public comment period will be considered in preparing the Final EIS. Public meetings to comment on the NBAF DEIS will be held at various locations near each alternative site location and in Washington, DC. Notification of the times and locations for the public meetings will be published in local news media and on the DHS Web site, *http://www.dhs.gov/nbaf* [click on Environmental Impact Statement]. The dates of the public review meetings are listed below.

The Public Meeting dates are:

1. Thursday, July 24, 2008, from 12:30 p.m. to 4:30 p.m. Washington, DC, Grand Hyatt Washington, 1000 H Street, NW., Washington, DC 20001.

2. Tuesday, July 29, 2008, from 12:30 p.m. to 4:30 p.m. and from 6 p.m. to 10 p.m. Butner, NC, Butner-Stem Middle School, 501 East D Street, Butner, NC 27509.

3. Thursday, July 31, 2008, from 12:30 p.m. to 4:30 p.m. and from 6 p.m. to 10 p.m. Manhattan, KS, Kansas State University, K-State Student Union, Manhattan, KS 66506.

4. Tuesday, August 5, 2008, from 12:30 p.m. to 4:30 p.m. and from 6 p.m. to 10 p.m. Flora, MS, First Baptist Church, Christian Life Center, 121 Center Street, Flora, MS 39071.

5. Thursday, August 7, 2008, from 12:30 p.m. to 4:30 p.m. and from 6 p.m. to 10 p.m. San Antonio, TX, Radisson Hill Country Resort, 9800 Westover Hills Boulevard, San Antonio, TX 78251.

6. Monday, August 11, 2008, from 6 p.m. to 10 p.m. Old Saybrook, CT, Saybrook Point Inn, Two Bridge Street, Old Saybrook, CT 06475.

7. Tuesday, August 12, 2008, from 6 p.m. to 10 p.m. Greenport, NY, Greenport School, 720 Front Street, Greenport, NY 11944.

8. Thursday, August 14, 2008, from 12:30 p.m. to 4:30 p.m. and from 6 p.m. to 10 p.m. Athens, GA, the University of Georgia, Center for Continuing Education, 1197 South Lumpkin Street, Athens, GA 30602.

Copies of the NBAF DEIS are available for review at the following locations:

Georgia

University of Georgia Main Library, 320 South Jackson Street, Athens, GA 30602.

Oconee County Library, 1080 Experiment Station Road, P.O. Box 837, Watkinsville, GA 30677.

Kansas

Manhattan Public Library, 629 Poyntz Avenue, Manhattan, KS 66502.

Hale Library, Kansas State University, Manhattan, KS 66506.

Mississippi

City of Flora Library, 144 Clark Street, Flora, MS 39071.

New York Site

Acton Public Library, 60 Old Boston Post Road, Old Saybrook, CT 06475.

Southold Free Library, 53705 Main Road, Southold, NY 11971.

North Carolina

Richard H. Thornton Library, 210 Main Street, Oxford, NC 27565–0339.

South Branch Library, 1547 South Campus Drive, Creedmoor, NC 27522.

Texas

Central Library, 600 Soledad, San Antonio, TX 78205.

Authority: 42 U.S.C. 4321–4347 (National Environmental Policy Act).

Dated: June 20, 2008.

Bruce Knight,

Under Secretary, Marketing and Regulatory Programs, USDA.

Jay M. Cohen,

Under Secretary, Science & Technology, DHS.

[FR Doc. E8–14526 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form N–648, Revision of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form N–648, Medical Certification for Disability Exceptions; OMB Control No. 1615–0060.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 14, 2008, at 73 FR 20058 allowing for a 60-day public comment period. USCIS received four comments for this information collection. The comments will be addressed in the supporting statement.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 28, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, for U.S. Citizenship and Immigration Services, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

When submitting comments by e-mail, please make sure to add OMB Control Number 1615–0060. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

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

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved information collection.

(2) *Title of the Form/Collection:* Medical Certification for Disability Exceptions.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N–648. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals and households. USCIS uses the Form N–648 medical certification issued by the licensed medical professional to substantiate a claim for an exception to the requirements of section 312(a) of the Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 20,000 responses at 2 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 40,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit: *http://www.regulations.gov/search/index.jsp.*

If additional information is required contact: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, Suite 3008, Washington, DC 20529, (202) 272–8377.

Dated: June 24, 2008.

Stephen Tarragon,

Acting Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. E8–14576 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Proposed Collection; Comment Request; Foreign Trade Zone Annual Reconciliation Certification and Record Keeping Requirement

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of existing collection of information: 1651–0051.

SUMMARY: The Department of Homeland Security, as part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Foreign Trade Zone Annual Reconciliation Certification and Record Keeping Requirement. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before August 26, 2008, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address the accuracy of the burden estimates and ways to minimize

the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Foreign Trade Zone Annual Reconciliation Certification and Record Keeping Requirement.

OMB Number: 1651–0051.

Form Number: None.

Abstract: Each Foreign Trade Zone Operator will be responsible for maintaining its inventory control in compliance with statue and regulations. The operator will furnish CBP an annual certification of their compliance.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 260.

Estimated Time per Respondent: 45 minutes.

Estimated Total Annual Burden Hours: 195.

Dated: June 23, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–14559 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Proposed Collection; Comment Request; Crew's Effects Declaration

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of existing collection of information: 1651–0020.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Crew's Effects Declaration. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before August 26, 2008, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Crew's Effects Declaration.

OMB Number: 1651–0020.

Form Number: CBP Form–1304.

Abstract: CBP Form–1304 contains a list of crew's effects that are accompanying them on the trip, which are required to be manifested, and also the statement of the master of the vessel attesting to the truthfulness of the merchandise being carried on board the vessel as crew's effects.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 9,000.

Estimated Number of Annual Responses: 206,100.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 17,326.

Dated: June 25, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–14560 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Proposed Collection; Comment Request; Vessel Entrance or Clearance Statement

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of existing collection of information: 1651–0019

SUMMARY: The Department of Homeland Security, as part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning Vessel Entrance of Clearance Statement. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before August 26, 2008, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection

techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Vessel Entrance or Clearance Statement Form.

OMB Number: 1651–0019.

Form Number: CBP Form 1300.

Abstract: This form is used by a master of a vessel to attest to the truthfulness of all other forms associated with the manifest.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses, Individuals, Institutions.

Estimated Number of Respondents: 12,000.

Estimated Number of Annual Responses: 264,000.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 21,991.

Dated: June 23, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–14561 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Certificate of Origin

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day Notice and request for comments; Extension of an existing information collection: 1651–0016; Proposed collection; comments requested.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Certificate of Origin. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments form the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (73 FR 15766–15767) on March 25, 2008, allowing for a 60-day comment period. One public comment was received. CBP will respond to this comment. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before July 28, 2008.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

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

(4) Minimize the burden of the collections 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, e.g., permitting electronic submission of responses.

Title: Certificate of Origin.

OMB Number: 1651–0016.

Form Number: CBP Form 3229.

Abstract: This certification is required to determine whether an importer is entitled to duty-free for goods which are the growth or product of a U.S. insular possession and which contain foreign materials representing no more than 70 percent of the goods total value.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 10.

Estimated Number of Annual Responses: 310.

Estimated Time per Response: 22 minutes.

Estimated Total Annual Burden Hours: 113.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202–344–1429.

Dated: June 18, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–14562 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Proposed Collection; Comment Request; Entry and Manifest of Merchandise Free of Duty

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of existing collection of information: 1651–0013.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Entry and Manifest of Merchandise Free of Duty. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before August 26, 2008, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Entry and Manifest of Merchandise Free of Duty.

OMB Number: 1651–0013.

Form Number: CBP Form–7523.

Abstract: CBP Form–7523 is used by carriers and importers as a manifest for the entry of merchandise free of duty under certain conditions, and by CBP to authorize the entry of such merchandise. It is also used by carriers to show that the articles being imported have been released to the importer or consignee.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 4,950.

Estimated Number of Annual Responses: 99,000.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 8,247.

Dated: June 23, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–14564 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Proposed Collection; Comment Request; Entry Summary and Continuation Sheet

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-day notice and request for comments; extension of existing collection of information: 1651–0022.

SUMMARY: The Department of Homeland Security, as part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Entry Summary and Continuation Sheet. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before August 26, 2008, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Bureau of Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; ways to enhance the quality, utility, and clarity of the information to be collected; (c) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (d) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Entry Summary and Continuation Sheet.

OMB Number: 1651–0022.

Form Number: CBP Form–7501, 7501A.

Abstract: Form CBP–7501 is used by CBP as a record of the impact transaction, to collect proper duty, taxes, exactions, certifications and enforcement endorsements.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 38,500.

Estimated Number of Annual Responses: 22,001,956.

Estimated Time per Respondent: 20 minutes.

Estimated Total Annual Burden Hours: 6,627,678.

Dated: June 23, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–14569 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Drawback Process Regulations

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day Notice and request for comments; Extension of an existing information collection with a change to the burden hours: 1651–0075; proposed collection; comments requested.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Drawback Process Regulations. This is a proposed extension with a change to the burden hours of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments form the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (73 FR 15764) on March 25, 2008, allowing for a 60-day comment period. Three public comments were received. CBP will respond to these comments. This notice allows for an additional 30 days for public comments.

DATES: Written comments should be received on or before July 28, 2008.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to: *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

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

(4) Minimize the burden of the collections 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, e.g., permitting electronic submission of responses.

Title: Drawback Process Regulations.

OMB Number: 1651–0075.

Form Number: Forms CBP–7551, 7552, 7553.

Abstract: The information is to be used by CBP officers to expedite the filing and processing of drawback claims, while maintaining necessary enforcement information to maintain effective administrative oversight over the drawback program.

Current Actions: This submission is being submitted to extend the expiration date with a change to the burden hours.

Type of Review: Extension (with change).

Affected Public: Businesses, Institutions.

Estimated Number of Respondents: 8,150.

Estimated Number of Annual Responses: 163,000.

Estimated Time Per Response: 34 minutes.

Estimated Total Annual Burden Hours: 93,250.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202–344–1429.

Dated: June 23, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–14570 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Proposed Collection; Comment Request; Petition for Remission or Mitigation of Forfeitures and Penalties

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of existing collection of information: 1651–0100.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Petition for Remission or Mitigation of Forfeitures and Penalties. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before August 26, 2008, to be assured of consideration.

ADDRESSES: Direct all written comments to the U.S. Customs and Border Protection, Information Services Group, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the U.S. Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: Petition for Remission or Mitigation of Forfeitures and Penalties.

OMB Number: 1651–0100.

Form Number: CBP Form 4609.

Abstract: Persons whose property is seized or who incur monetary penalties due to violations of the Tariff Act are entitled to seek remission or mitigation by means of an informal appeal. This form gives the violator the opportunity to claim mitigation and provides a record of such administrative appeals.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 28,000.

Estimated Number of Annual Responses: 28,000.

Estimated Time Per Respondent: 14 minutes.

Estimated Total Annual Burden Hours: 6,500.

Dated: June 23, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–14571 Filed 6–26–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5186–N–26]

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, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7266, 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 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*, No. 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 Theresa Rita, 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: COAST GUARD: Commandant, United States Coast Guard, Attn: Teresa Sheinberg, 2100 Second St., SW., Rm 6109, Washington, DC 20593–0001; (202) 267–6142; ENERGY: Mr. Mark Price, Department of Energy, Office of Engineering & Construction Management, MA–50, 1000 Independence Ave., SW., Washington, DC 20585: (202) 586–5422; GSA: Mr. John Smith, Deputy Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th & F Streets, NW., Washington, DC 20405; (202) 501–0084; NAVY: Mrs. Mary Arndt, Acting Director, Department of the Navy, Real Estate Services, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE., Suite 1000, Washington, DC 20374–5065; (202) 685–9305; (These are not toll-free numbers.)

Dated: June 19, 2008.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

Title V, Federal Surplus Property Program Federal Register Report for 06/27/2008

Suitable/Available Properties

Building

Arizona

Water Conservation Lab
4331 E. Broadway Rd.
Phoenix AZ 85040
Landholding Agency: GSA
Property Number: 54200820013
Status: Excess
GSA Number: 9–A–AZ–846–1
Comments: 11365 sq. ft. main bldg w/11 additional bldgs. & 66 paved parking spaces, easement restrictions, zoning issue

North Dakota

Facility F–O
Foxtrot
Grand Forks ND
Landholding Agency: GSA
Property Number: 54200820015
Status: Surplus
GSA Number: 7–D–ND–0500

Comments: 5850 sq. ft. facility, asbestos/PCB's/lead based paint, restrictions and covenants

Suitable/Available Properties

Building

Oklahoma

Maintenance Site
Rt. 1
Tupelo OK 74572
Landholding Agency: GSA
Property Number: 54200820016
Status: Excess
GSA Number: 7–GR–OK–0574
Comments: Office/garage/storage, easement restrictions

Land

Texas

FAA Outer Marker 18 R/L VYN
1420 Lakeside Pkwy
Flower Mound TX 75028
Landholding Agency: GSA
Property Number: 54200820017
Status: Surplus
GSA Number: 7–U–TX–1090
Comments: 1.428 acres, radar facility

FAA Outer Marker 31R RAA
1600 Cooper Drive
Irving TX 75061
Landholding Agency: GSA
Property Number: 54200820018
Status: Surplus
GSA Number: 7–U–TX–1095
Comments: 0.305 acre, radar facility

Suitable/Available Properties

Land

Texas

FAA Outer Marker 35R AJQ
300 W. Shady Grove
Grand Prairie TX 75050
Landholding Agency: GSA
Property Number: 54200820019
Status: Surplus
GSA Number: 7–U–TX–1094
Comments: 0.674 acre, radar facility

Unsuitable Properties

Building

California

Bldg. 19
USCG Integrated Sup Comm
San Pedro CA 90731
Landholding Agency: Coast Guard
Property Number: 88200820004
Status: Unutilized
Reasons: Extensive deterioration

Unsuitable Properties

Building

Hawaii

Bldg. 1981
Naval Station
Pearl Harbor HI 96860
Landholding Agency: Navy
Property Number: 77200820038
Status: Unutilized
Reasons: Extensive deterioration

Bldg. 17
Naval Station
Pearl Harbor HI 96860
Landholding Agency: Navy
Property Number: 77200820039
Status: Excess
Reasons: Extensive deterioration

Bldg. 88
Naval Station
Ford Island
Pearl Harbor HI 96860
Landholding Agency: Navy
Property Number: 77200820040
Status: Excess
Reasons: Extensive deterioration

Unsuitable Properties

Building

Idaho

RCLR Facility
State Hwy 69
Meridian ID 83704
Landholding Agency: GSA
Property Number: 54200820014
Status: Excess
GSA Number: 9–U–ID–566
Reasons: Within 2000 ft. of flammable or explosive material

Illinois

Bldg. 40
Argonne National Lab
DuPage IL 60439
Landholding Agency: Energy
Property Number: 41200820007
Status: Excess
Reasons: Contamination; Secured Area

Rhode Island

Bldgs. 348, 85CHI
Naval Station
Newport RI
Landholding Agency: Navy
Property Number: 77200820043
Status: Unutilized
Reasons: Secured Area

Unsuitable Properties

Building

Rhode Island

Facility 670
Naval Station
Harbor Island
Newport RI 02841
Landholding Agency: Navy
Property Number: 77200820044
Status: Excess
Reasons: Extensive deterioration; Secured Area

Land

North Carolina

0.23 acres/French Creek
Marine Corps Base
Camp Lejeune NC
Landholding Agency: Navy
Property Number: 77200820041
Status: Underutilized
Reasons: Secured Area

0.23 acres/Onslow Beach
Marine Corps Base
Camp Lejeune NC
Landholding Agency: Navy
Property Number: 77200820042
Status: Underutilized
Reasons: Secured Area

Unsuitable Properties

Land

Virginia

FAA Outer Marker 19R
Norman's Station Rd.
Chantilly VA 20151
Landholding Agency: GSA
Property Number: 54200820020
Status: Surplus
GSA Number: 11–VA–1103AA
Reasons: Within airport runway clear zone; Within 2000 ft. of flammable or explosive material

[FR Doc. E8–14290 Filed 6–26–08; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Federal Housing Enterprise Oversight; Privacy Act of 1974, as Amended; Amendment of Systems of Records

AGENCY: Office of Federal Housing Enterprise Oversight, HUD.

ACTION: Notice of amendment to systems of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a (Privacy Act), the Office of Federal Housing Enterprise Oversight (OFHEO) is issuing public notice of its intent to revise one existing system of records and delete one existing system of records. The systems are being revised or deleted as a result of reevaluation of the manner in which OFHEO maintains the records. OFHEO is combining these two systems of records into one expanded system, therefore, OFHEO–05, Senior Staff Biography System will be deleted, and the number OFHEO–05 reserved for future use. The revised system, OFHEO–03, Employee Identification Card System will be renamed the Staff Information and Identification System and will include information formerly maintained in OFHEO–05, Senior Staff Biography System. Revisions will incorporate administrative changes that have taken place since the last publication of OFHEO–03 at 63 FR 9007 on February 23, 1998.

The revised system of records will consist of information on employees and contractors in order to issue temporary identification cards; provide biographical information to the media and other groups which request information on OFHEO staff as speakers or panel participants; and provide a resource to allow management to identify employees and contractors by their photograph, status and organizational office.

DATES: Written comments must be received by or before July 28, 2008. If no public comments are received, the proposed new system of records will become effective on August 6, 2008.

ADDRESSES: You may submit comments, identified by ''Staff Information and Identification System,'' by any of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Agency Web Site: http://www.ofheo.gov.* Follow the instructions for submitting comments on the OFHEO Web site.
- *E-mail: RegComments@OFHEO.gov.* Please include ''Staff Information and Identification System'' in the subject line of the message.
- *Mail:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments ''Staff Information and Identification System,'' Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Washington, DC 20552.
- *Hand Delivery/Courier:* The address for hand delivery/courier is: Alfred M. Pollard, General Counsel, Attention: Comments ''Staff Information and Identification System,'' Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Washington, DC 20552. The package should be logged at the Guard Desk, First Floor, on business days between 9 a.m. and 3 p.m.

See **SUPPLEMENTARY INFORMATION** for additional information on submission and posting of comments.

FOR FURTHER INFORMATION CONTACT: Mark D. Laponsky, Deputy General Counsel, telephone (202) 414–3832 (not a toll-free number); Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Deaf is (800) 877–8339 (TDD *Only*).

SUPPLEMENTARY INFORMATION:

Instructions: OFHEO invites comments on the proposed revision to an existing system of records described in this notice. Comments should include the agency name and the reference ''Staff Information and Identification System'' as well as your name and other contact information in the body of your comment. OFHEO further requests that comments submitted in hard copy also be accompanied by the electronic version in Microsoft® Word or in portable document format (PDF) on 3.5″ disk or CD–ROM.

Posting and Public Availability of Comments: All comments received will be posted without change to *http://www.regulations.gov* as well as on the OFHEO Internet Web site at *http://www.ofheo.gov* and will include any personal information provided. In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Washington, DC. To make an appointment to inspect comments, please call the Office of General Counsel at (202) 414–6924.

Introduction: This notice informs the public that OFHEO proposes to revise an existing system of records and delete an obsolete system of records. This notice satisfies the Privacy Act requirement that agencies publish notices in the **Federal Register** describing new or altered systems of records. The revised system of records is:

OFHEO–03, Staff Information and Identification System (formerly known as the Employee Identification Card System)

The deleted system of records is:

OFHEO–05, Senior Staff Biography System

As required by 5 U.S.C. 552a(r) of the Privacy Act, and pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, OFHEO is filing a report describing the amended systems of records covered by this notice to the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget. The proposed alterations to an existing system of records, as described above, are set forth in its entirety below.

Dated: June 23, 2008.

James B. Lockhart III,

Director.

OFHEO–03

SYSTEM NAME:

Staff Information and Identification System.

SYSTEM LOCATION:

The Office of Management Planning, OFHEO, 1700 G Street, NW., Washington, DC 20552, and any alternate work site utilized by employees of the Office of Federal Housing Enterprise Oversight (OFHEO) or individuals assisting such employees.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

OFHEO employees and contractor personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include the individual's name, photograph, temporary identification card issue and expiration date, status, organizational office, educational background, experience, professional accomplishment, and affiliations.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Safety and Soundness Act (12 U.S.C. 4513(b)(9)).

PURPOSE(S):

Information in this system will be used by OFHEO to establish and maintain a repository of information on employees and contractors in order to issue temporary identification cards; to provide biographical information to the media and other groups which request information on OFHEO staff as speakers or panel participants; and to provide a resource to allow management to identify employees and contractors by their photograph, status and organizational office.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the conditions of disclosure under 5 U.S.C.552a(b) and in addition to the general routine uses identified in the Prefatory Statement of General Routine Uses, 63 FR 9007 (February 23, 1998), it shall be a routine use to disclose information contained in this system for the purposes and to the users identified below:

1. To appropriate persons, consultants, contractors, entities or others in the event of a breach of data contained in the system, as necessary for the purposes of responding to and remedying a breach.
2. To first responders and others as necessary to provide emergency response or evacuation assistance to covered individuals.
3. To appropriate individuals in the news media, public affairs personnel, and groups which request OFHEO staff as speakers or panel participants.
4. To appropriate persons, consultants, and contractors to allow positive identification of employees.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures may be made from this system pursuant to 5 U.S.C. 552a(b)(12) to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) when OFHEO is trying to collect a claim of the Government under a law, except the Internal Revenue Code of 1986, in accordance with 31 U.S.C. 3711(e).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records will be stored in both electronic and paper format. Paper records are to be maintained in file folders or binders. Computer files are to be maintained on magnetic tape, CD, or other machine readable format.

RETRIEVABILITY:

Records will be retrieved by the individual's name, identification card issue date, status, or organizational office.

SAFEGUARDS:

Access is restricted to OFHEO employees and contractors who require the information in performing their official duties. Access to computerized records is limited, through use of access codes and entry logs to those whose official duties require access. Paper records are maintained in locked cabinets.

RETENTION AND DISPOSAL:

Records will be maintained and disposed of in accordance with the National Archives and Records Administration General Records Schedule 18, Item 19.

SYSTEM MANAGER(S) AND ADDRESS:

Chief Human Capital Officer, Office of Human Resources Management, OFHEO, 1700 G Street, NW., Washington, DC 20552.

Associate Director, Office of Management Planning, OFHEO, 1700 G Street, NW., Washington, DC 20552.

NOTIFICATION PROCEDURE:

An individual can determine if this system contains a record pertaining to him/her by sending a request in writing, signed, to Contact the Privacy Act Officer, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Washington, DC 20552.

When requesting notification of or access to records covered by this Notice, an individual should provide his/her full name, date of birth, agency name, and work location. An individual requesting notification of records in person must provide identity documents sufficient to satisfy the custodian of the records that the requester is entitled to access, such as a government-issued photo ID. Individuals requesting notification via mail or telephone must furnish, at minimum, name, date of birth, social security number, and home address in order to establish identity.

RECORD ACCESS PROCEDURES:

The OFHEO regulation for providing access to records appears at 12 CFR part 1702. If additional information or assistance is required, contact the Privacy Act Officer, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Washington, DC 20552.

CONTESTING RECORD PROCEDURES:

The procedures for contesting initial denials for access to or amendment of records appears at 12 CFR part 1702. If additional information or assistance is required, contact the Privacy Act Officer at OFHEO, 1700 G Street, NW., Washington, DC 20552.

RECORD SOURCE CATEGORIES:

The information is obtained from the individuals on whom the information is maintained, from the OFHEO Office of Human Resources Management staff, the Office of Management Planning staff, and from the Office of Budget & Financial Management.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–14693 Filed 6–26–08; 8:45 am]

BILLING CODE 4220–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R9-NCTC-2008-N0157] [97310-1661-0030]

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; OMB Control Number 1018-0115, Application for Training, National Conservation Training Center

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. The ICR, which is summarized below, describes the nature of the collection and the estimated burden and cost. This IC is scheduled to expire on June 30, 2008. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before July 28, 2008.

ADDRESSES: Send your comments and suggestions on this ICR to the Desk Officer for the Department of the Interior at OMB-OIRA at (202) 395-6566 (fax) or OIRA_DOCKET@OMB.eop.gov (e-mail). Please provide a copy of your comments to Hope Grey, Information Collection Clearance Officer, Fish and Wildlife Service, MS 222-ARLSQ, 4401 North Fairfax Drive, Arlington, VA 22203 (mail); (703) 358-2269 (fax); or hope_grey@fws.gov (e-mail).

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey by mail, fax, or e-mail (see ADDRESSES) or by telephone at (703) 358–2482.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1018-0115.

Title: Application for Training, National Conservation Training Center.

Service Form Number(s): 3-2193.

Type of Request: Extension of a currently approved collection.

Affected Public: Persons who wish to participate in training given at or sponsored by the National Conservation Training Center (NCTC).

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion when applying for training at NCTC.

Estimated Annual Number of Respondents: 500.

Estimated Total Annual Responses: 500.

Estimated Time Per Response: 10 minutes.

Estimated Total Annual Burden Hours: 83.

Abstract: The Fish and Wildlife Service National Conservation Training Center in Shepherdstown, West Virginia, provides natural resource and other professional training for Service employees, employees of other Federal agencies, and other affiliations, including State agencies, private individuals, not-for-profit organizations, and university personnel. FWS Form 3-2193 (Training Application) is a quick and easy method for prospective non-Department of the Interior students to request training. We encourage applicants to use FWS Form 3-2193 and to submit their requests electronically. However, we do not require applicants to complete both a training form required by their agency and FWS Form 3-2193. NCTC will accept any single training request as long as each submission identifies the name, address, and phone number of the applicant, sponsoring agency, class name, start date, and all required financial payment information.

NCTC uses data from the form to generate class rosters, class transcripts, and statistics, and as a budgeting tool

for projecting training requirements. It is also used to track attendance, mandatory requirements, tuition, and invoicing for all NCTC-sponsored courses both on- and off-site.

Comments: On April 25, 2008, we published in the Federal Register (73 FR 22430) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on June 24, 2008. We received one comment. The comment was directed to the subject matter, validity, and necessity of the training and not at the need for the information collection. The commenter stated that training does not help the general public and that NCTC is a private hunting club. The commenter believes that the training we provide is focused on gun, hunting, and violence proponents.

All training courses that NCTC offers, with the exception of some bureau specific courses, are open to members of the general public who have the required background experience or knowledge to allow their full understanding of the subject matter. Very few of our training courses have an emphasis on guns and hunting. Those courses that do touch on this subject are presented in the context of refuge and wildlife management and law enforcement. We have not made any changes to the collection in response to this comment.

We again invite comments concerning this information collection on:

(1) whether or not the collection of information is necessary, including whether or not the information will have practical utility;

(2) the accuracy of our estimate of the burden for this 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.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Hope Grey,

Information Collection Clearance Officer, Fish and Wildlife Service.

FR Doc. E8–14582 Filed 6–26–08; 8:45 am

BILLING CODE 4310–55–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R9-MB-2008-N00169] [91200-1231-9BPP-L2]

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; OMB Control Number 1018-0103; Conservation Order for Control of Midcontinent Light Geese

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. The ICR, which is summarized below, describes the nature of the collection and the estimated burden and cost. This ICR is scheduled to expire on June 30, 2008. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before July 28, 2008.

ADDRESSES: Send your comments and suggestions on this ICR to the Desk Officer for the Department of the Interior at OMB-OIRA at (202) 395-6566 (fax) or OIRA_DOCKET@OMB.eop.gov (e-mail). Please provide a copy of your comments to Hope Grey, Information Collection Clearance Officer, Fish and Wildlife Service, MS 222-ARLSQ, 4401 North Fairfax Drive, Arlington, VA 22203 (mail); (703) 358-2269 (fax); or hope_grey@fws.gov (e-mail).

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey by mail, fax, or e-mail (see ADDRESSES) or by telephone at (703) 358–2482.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1018-0103.

Title: Conservation Order for Control of Midcontinent Light Geese, 50 CFR 21.60.

Service Form Number(s): None.

Type of Request: Extension of currently approved collection.

Affected Public: State and tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually.

Number of Respondents: 24.

Number of Annual Responses: 24.

Completion Time per Response: 74 hours.

Total Annual Burden Hours: 1,776 hours.

Abstract: The number of light geese (lesser snow, greater snow, and Ross' geese) in the midcontinent region has nearly quadrupled during the past several decades due to a decline in adult mortality and an increase in winter survival. We refer to these species and subspecies as light geese because of their light coloration as opposed to dark geese such as white-fronted or Canada geese. Because of their feeding activity, light geese have become seriously injurious to their habitat as well as to habitat important to other migratory birds. This poses a serious threat to the short- and long-term health and status of some migratory bird populations. We believe that the number of light geese in the midcontinent region has exceeded long-term sustainable levels for their arctic and subarctic breeding habitats and that the populations must be reduced. 50 CFR 21 provides authority for the management of overabundant, midcontinent light geese.

On February 16, 1999, we published a final rule (64 FR 7517) that established a conservation order for midcontinent light geese (50 CFR 21.60). This regulation authorizes States and tribes in the midcontinent region to control midcontinent light geese within the United States through the use of alternative regulatory strategies. The conservation order authorizes States/tribes to implement population control measures without having to obtain a permit, thus significantly reducing their administrative burden. The conservation order is a streamlined process that affords an efficient and effective population reduction strategy, rather than addressing the issue through our permitting process. Furthermore, this strategy precludes the use of more drastic and costly direct population-reduction measures such as trapping and culling geese.

States/tribes that participate in the conservation order must inform and brief all participants on the requirements in 50 CFR 21.60 and conservation order conditions that apply to the implementation of light geese control measures. Participating States/tribes must collect information

on the number of birds taken during control efforts, the methods by which they were taken, and the date on which they were taken. We use this information to administer the conservation order and, particularly, to monitor the effectiveness of control strategies and to protect migratory birds. Each participating State/tribe must submit an annual report summarizing the activities it conducted.

Comments: On April 25, 2008, we published in the Federal Register (73 FR 22429) a notice of our intent to request that OMB renew authority for this information collection. In that notice, we solicited public comments for 60 days, ending on June 24, 2008. We received one comment during this period. The commenter objected to the killing of geese and did not address the information collection requirements. We did not make any changes to our information collection as a result of this comment.

We again invite comments concerning this information collection on:

(1) whether or not the collection of information is necessary, including whether or not the information will have practical utility;

(2) the accuracy of our estimate of the burden for this 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.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Hope Grey,

Information Collection Clearance Officer, Fish and Wildlife Service.

FR Doc. E8–14583 Filed 6–26–08; 8:45am

BILLING CODE 4310–55–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2008–N0154; 80221–1113–0000–F5]

Endangered Species Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comment.

SUMMARY: We invite the public to comment on the following applications to conduct certain activities with endangered species.

DATES: Comments on these permit applications must be received on or before July 28, 2008.

ADDRESSES: Written data or comments should be submitted to the U.S. Fish and Wildlife Service, Endangered Species Program Manager, Region 8, 2800 Cottage Way, Room W–2606, Sacramento, CA 95825 (telephone: 916–414–6464; fax: 916–414–6486).

Please refer to the respective permit number for each application when submitting comments. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public.

FOR FURTHER INFORMATION CONTACT: Daniel Marquez, Fish and Wildlife Biologist, see **ADDRESSES**, (telephone: 760–431–9440; fax: 760–431–9624).

SUPPLEMENTARY INFORMATION: The following applicants have applied for scientific research permits to conduct certain activities with endangered species pursuant to section 10(a)(1)(A) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*). The U.S. Fish and Wildlife Service (''we'') solicits review and comment from local, State, and Federal agencies, and the public on the following permit requests. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Permit No. TE–097845

Applicant: Mantech SRS Technologies, Lompoc, California.

The applicant requests an amendment to take (capture, collect, and kill) the Conservancy fairy shrimp (*Branchinecta conservatio*), the longhorn fairy shrimp (*Branchinecta longiantenna*), the Riverside fairy shrimp (*Streptocephalus wootoni*), the San Diego fairy shrimp (*Branchinecta sandiegonensis*), and the vernal pool tadpole shrimp (*Lepidurus packardi*) in conjunction with surveys throughout the range of each species in California; and take (survey by pursuit) the El Segundo Blue butterfly (*Euphilotes battoides allyni*) in conjunction with surveys in Ventura and Santa Barbara Counties, California for the purpose of enhancing their survival.

Permit No. TE–069171

Applicant: National Park Service, Thousand Oaks, California.

The applicant requests an amendment to remove/reduce to possession the *Astragalus brauntonii* (Braunton's milkvetch) from federal lands in conjunction genetic research and taxonomic status studies throughout the range of the species in California, for the purpose of enhancing their survival.

Permit No. TE–147533

Applicant: Jeffery J. Mitchell, San Francisco, California.

The applicant requests an amendment to take (survey, capture, collect biological samples, and release) the California tiger salamander (*Ambystoma californiense*) in conjunction with biological research throughout the range of the species in California, for the purpose of enhancing its survival.

Permit No. TE–185595

Applicant: Kelly E. Buja, Sacramento, California.

The applicant requests a permit to take (capture, collect, and kill) the Conservancy fairy shrimp (*Branchinecta conservatio*), the longhorn fairy shrimp (*Branchinecta longiantenna*), the Riverside fairy shrimp (*Streptocephalus wootoni*), the San Diego fairy shrimp (*Branchinecta sandiegonensis*), and the vernal pool tadpole shrimp (*Lepidurus packardi*) in conjunction with surveys throughout the range of each species in California, for the purpose of enhancing their survival.

We solicit public review and comment on each of these recovery permit applications. Comments and materials we receive will be available for public inspection, by appointment, during normal business hours at the address listed in the **ADDRESSES** section of this notice.

Dated: June 23, 2008.

Michael Fris,

Acting Regional Director, Region 8, Sacramento, California.

[FR Doc. E8–14581 Filed 6–26–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–100–08–1310–DB]

Notice of Availability of a Final Supplemental Environmental Impact Statement for the Pinedale Anticline Oil and Gas Exploration and Development Project, Sublette County, WY

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et seq.*) the Bureau of Land Management (BLM) has prepared a Final Supplemental Environmental Impact Statement (FSEIS) that analyzes additional oil and gas development in the Pinedale Anticline Project Area (PAPA).

DATES: The FSEIS will be available for review for 30 days following the date the Environmental Protection Agency publishes their Notice of Availability in the **Federal Register**. A Record of Decision (ROD) will be prepared following the 30-day review period.

FOR FURTHER INFORMATION, CONTACT: Caleb Hiner, BLM Project Manager, 768 West Pine Street, P.O. Box 768, Pinedale, Wyoming 82941. Electronic mail may be sent to: *Caleb_Hiner@blm.gov* with ''PAPA FSEIS Information Request'' in the subject line. The FSEIS will be posted at *http://www.blm.gov/wy/st/en/info/NEPA/pfodocs/anticline/seis.html* when available.

SUPPLEMENTARY INFORMATION: The BLM conducted NEPA analysis and issued a ROD for the Pinedale Anticline Oil and Gas Exploration and Development Project in July 2000. The BLM conducted this analysis in response to increasing numbers of operators requesting approval to explore for and develop natural gas on the Pinedale Anticline. The 2000 PAPA ROD established protection of big game crucial winter ranges from oil and gas developments (well drilling and completion) during the winter months, and therefore did not include analysis of the potential impacts of oil and gas development activities (specifically drilling and completions) to big game on crucial winter ranges during the period of November 15 through April 30. The PAPA ROD provided that the BLM could grant limited exceptions to this winter closure period based on current conditions such as presence of wintering animals or depth of snow cover. Finally, the analysis in the PAPA EIS considered a total of 900 wells drilled with 700 producing well pads. The PAPA ROD stated that if the level of proposed development exceeds that analyzed in the EIS, BLM would conduct additional environmental analysis. There are currently approximately 460 producing wells in the PAPA.

Starting in winter 2002–2003, the BLM authorized Questar Exploration and Development Company to continue winter gas development operations at one well pad within big game crucial winter range with the requirement that they work closely with the Wyoming Game and Fish Department in its study of impacts to the Sublette Mule Deer. Since then, other operators within the PAPA have expressed interest in conducting gas development activities including year-round drilling within big game crucial winter range. In summer 2005, Anschutz, Shell, and Ultra submitted a proposal to the BLM for year-round drilling demonstration project on three well pads within their leaseholds for one year. In September 2005, the BLM issued a Decision Record to allow them to proceed (ASU Year-Round Drilling Demonstration Project, September 2005).

In 2005, BLM received a proposal for continued and expanded long-term development of natural gas resources in the PAPA from Questar Exploration and Production, Shell Exploration and Production Company, and Ultra Resources Inc. ('The Operators'). The Operators proposed to conduct year-round drilling and completions in concentrated development areas within a core development area coinciding with the Anticline Crest in the PAPA. The Operators proposed an additional 4,399 wells on approximately 10-acre bottom hole spacing from an additional 250 well pads. The proposed development included construction of new well pads and substantial expansion of existing well pads to allow for multiple wells to be drilled from a pad. In addition, the BLM has determined that there is a need for new pipeline corridors between the PAPA and gas processing plants in southwestern Wyoming. Therefore, the FSEIS also includes analysis of potential new corridors.

The PAPA encompasses approximately 198,034 acres of primarily Federal lands (nearly 80 percent), and State and private land. Approximately 83 percent of the mineral estate underlying the PAPA is federally-owned. The BLM has identified the following resources that may be adversely impacted by the proposal: surface and ground water resources; air quality; wildlife and their habitats; reclamation; visual resources; transportation; noxious weed control; grazing, cultural and paleontological resources; wetland and riparian resources; threatened and endangered animal and plant species; and socioeconomic resources.

The BLM's Notice of Intent (NOI) to prepare a SEIS was printed in the **Federal Register** on October 21, 2005. A Notice of Availability (NOA) of the Draft SEIS was published in the **Federal Register** on December 15, 2006. The public comment period on the Draft SEIS closed in April 2006. Based upon public comment, the BLM determined two additional alternatives needed to be analyzed and made available for public review. A NOA for Revised Draft SEIS was published in the **Federal Register** on December 28, 2007. The comment period on the Revised Draft SEIS closed on February 11, 2008.

The FSEIS describes and analyzes five alternatives, including the No Action Alternative and The Operators proposed action. A summary of the alternatives follows:

(A) The No Action Alternative would continue development on the Pinedale Anticline under the conditions imposed by the 2000 PAPA ROD. The Operator's proposal for year-round access would be denied. This alternative does not provide for full resource recovery.

(B) Alternative 2, The Operators proposed action, includes year-round development of up to 4,399 additional wells. Development would occur in three areas of concentrated development within a core area. Tier 2 equivalent emission controls would be installed on drilling rig engines in 29 of 48 drilling rigs in 2009. The Operators have also committed to 3:1 offsite mitigation for wildlife, if necessary.

(C) Alternative 3 considers the same project components as Alternative 2; however implementation would be phased spatially. It analyzes a smaller core area, with five areas of development; year-round access would be limited by area. The goal of Alternative 3 is to minimize surface disturbance in some areas while maximizing development in other areas. Air quality mitigation to reduce impacts

in nearby sensitive areas is included in this alternative.

(D) Alternative 4, the BLM Preferred Alternative, is the result of comments received on the Draft SEIS. This alternative expands the core area slightly as compared to Alternatives 2 and 3, and delineates a potential development area around the core. Similar to Alternatives 2 and 3 the core area is broken into five development areas. The alternative also analyzes spatial phasing of development and applies Operator offered mitigation measures including Federal suspended leases and areas of no surface occupancy on areas outside the core of the PAPA. Adaptive management and a compensatory mitigation fund are also important elements of this alternative. Additional air quality mitigation is also included to further reduce impacts.

(E) Alternative 5 describes development of the full Operator proposed number of new wells (4,399) under conditions similar to the 2000 PAPA ROD, and without winter access in restricted wildlife habitats.

James K. Murkin,

Acting Associate State Director.

[FR Doc. E8–14493 Filed 6–26–08; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–921–03–1320–EL; COC–73016]

Notice of Invitation for Coal Exploration License Application, Peabody Coal Company, COC–73016; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Invitation for Coal Exploration License Application, Peabody Coal Company.

SUMMARY: Pursuant to the Mineral Leasing Act of February 25, 1920, as amended, and to Title 43, Code of Federal Regulations, Subpart 3410, members of the public are hereby invited to participate with Peabody Coal Company, in a program for the exploration of unleased coal deposits owned by the United States of America containing approximately 3,980.0 acres in Morgan & Routt County, Colorado.

DATES: Written Notice of Intent to Participate should be addressed to the attention of the following persons and must be received by them within 30 days after publication of this Notice of Invitation in the **Federal Register**.

ADDRESSES: Kurt M. Barton, CO–921, Solid Minerals Staff, Division of Energy, Lands and Minerals, Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado 80215; and, Peabody Coal Company, PO Box 373, St. Louis, MO 63166.

SUPPLEMENTARY INFORMATION: The application for coal exploration license is available for public inspection during normal business hours under serial number COC–73016 at the Bureau of Land Management, Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215; and at the Little Snake Field Office, 455 Emerson St., Craig, Colorado 81625. Any party electing to participate in this program must share all costs on a pro rata basis with Peabody Coal Company, and with any other party or parties who elect to participate.

Kurt M. Barton,

Solid Minerals Staff, Division of Energy, Lands and Minerals.

[FR Doc. E8–14614 Filed 6–26–08; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Environmental Documents Prepared for Proposed Oil and Gas Operations on the Gulf of Mexico Outer Continental Shelf (OCS)

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the Availability of Environmental Documents. Prepared for OCS Mineral Proposals on the Gulf of Mexico OCS.

SUMMARY: Minerals Management Service (MMS), in accordance with Federal Regulations that implement the National Environmental Policy Act (NEPA), announces the availability of NEPA-related Site-Specific Environmental Assessments (SEA) and Findings of No Significant Impact (FONSI), prepared by MMS for the following oil and gas activities proposed on the Gulf of Mexico OCS.

FOR FURTHER INFORMATION CONTACT: Public Information Unit, Information Services Section at the number below. Minerals Management Service, Gulf of Mexico OCS Region, Attention: Public Information Office (MS 5034), 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana 70123–2394, or by calling 1–800–200–GULF.

SUPPLEMENTARY INFORMATION: MMS prepares SEAs and FONSIs for proposals that relate to exploration for and the development/production of oil and gas resources on the Gulf of Mexico OCS. These SEAs examine the potential environmental effects of activities described in the proposals and present MMS conclusions regarding the significance of those effects. Environmental Assessments are used as a basis for determining whether or not approval of the proposals constitutes major Federal actions that significantly affect the quality of the human environment in the sense of NEPA Section 102(2)(C). A FONSI is prepared in those instances where MMS finds that approval will not result in significant effects on the quality of the human environment. The FONSI briefly presents the basis for that finding and includes a summary or copy of the SEA.

This notice constitutes the public notice of availability of environmental documents required under the NEPA Regulations.

This listing includes all proposals for which the Gulf of Mexico OCS Region prepared a FONSI in the period subsequent to publication of the preceding notice.

Activity/operator	Location	Date
Murphy Exploration and Production Company-USA, Initial Exploration Plan, SEA N–9060.	De Soto Canyon, Block 838, Lease OCS–G 10475, located 95 miles from the nearest Louisiana shoreline.	11/2/2007
Apache Corporation, Supplemental Exploration Plan, SEA S–7139.	High Island, Block A–376, Lease OCS–G 02754, located 120 miles from the nearest Louisiana shoreline.	1/8/2008
El Paso Production Oil & Gas Company, Structure Removal, SEA ES/SR 05–157A.	Vermilion, Block 102, Lease OCS–G 03393, located 29 miles from the nearest Louisiana shoreline.	1/8/2008
El Paso Production Oil & Gas Company, Structure Removal, SEA ES/SR 06–092A.	Eugene Island, Block 53, Lease OCS–G 00479, located 15 miles from the nearest Louisiana shoreline.	1/10/2008
W & T Offshore, Inc., Structure Removal, SEA ES/SR 07–160 ..	Ship Shoal, Block 201, Lease OCS–G 05557, located 42 miles from the nearest Louisiana shoreline.	1/10/2008

Activity/operator	Location	Date
Energy Partners, LTD, Structure Removal, SEA ES/SR 07–090B.	High Island, Block 72, Lease OCS–G 22231, located 20 miles from the nearest Texas shoreline.	1/12/2008
TGS-NOPEC Geophysical Company, Geological & Geophysical Prospecting for Mineral Resources, SEA T07–23.	Located in the western Gulf of Mexico south of Freeport, Texas	1/12/2008
ATP Oil & Gas Corporation, Structure Removal, SEA ES/SR 07–154.	Eugene Island (South Addition), Block 281, Lease OCS–G 09591, located 60 miles from the nearest Louisiana shoreline.	1/14/2008
W & T Offshore, Inc., Structure Removal, SEA ES/SR 07–159 ..	Ship Shoal, Block 202, Lease OCS–G 05558, located 42 miles from the nearest Louisiana shoreline.	1/14/2008
Chevron U.S.A., Inc., Revised Exploration Plan, SEA R–4775 ...	Atwater Valley, Block 138, Lease OCS–G 23018, located 79 miles south of Venice.	1/16/2008
Maritech Resources, Inc., Structure Removal, SEA ES/SR 07–143.	Eugene Island, Block 116, Lease OCS–G 00478, located 29 miles from the nearest Louisiana shoreline.	1/17/2008
Hydro Gulf of Mexico, LLC, Structure Removal, SEA ES/SR 07–120.	High Island, Block 202, Lease OCS–G 14870, located 33 miles from the nearest Texas shoreline.	1/17/2008
ATP Oil & Gas Corporation, Structure Removal, SEA ES/SR 07–144.	West Cameron, Block 194, Lease OCS–G 09402, located 28 miles from the nearest Louisiana shoreline.	1/17/2008
Energy Resource Technology, Inc., Structure Removal, SEA ES/SR 06–009A.	Brazos, Block 452, Lease OCS–G 04713, located 13 miles from the nearest Texas.	1/23/2008
Hydro Gulf of Mexico, LLC, Structure Removal, SEA ES/SR 07–126.	High Island, Block 197, Lease OCS–G 22238, located 27 miles from the nearest Texas shoreline.	1/25/2008
Arena Offshore, LLC, Structure Removal, SEA ES/SR APM HIA346–001.	High Island, Block A346, Lease OCS–G 22272, located 112 miles from the nearest Louisiana shoreline.	1/25/2008
Hunt Oil Company, Structure Removal, SEA ES/SR 08–004	High Island, Block A530, Lease OCS–G 18956, located 95 miles from the nearest Texas shoreline.	1/25/2008
Hydro Gulf of Mexico, LLC, Structure Removal, SEA ES/SR 07–123.	High Island, Block A7, Lease OCS–G 15781, located 33 miles from the nearest Texas shoreline.	1/25/2008
Apache Corporation, Structure Removal, SEA ES/SR 07–153 ...	Vermilion, Block 112, OCS–G 10659, located 29 miles from the nearest Louisiana shoreline.	1/25/2008
Forest Oil Corporation, Structure Removal, SEA ES/SR 08–003	Vermilion, Block 35, Lease OCS–G 00549, located 7 miles from the nearest Louisiana shoreline.	1/25/2008
ATP Oil & Gas Corporation, Structure Removal, SEA ES/SR 07–146.	West Cameron, Block 101, Lease OCS–G 16115, located 13 miles from the nearest Louisiana shoreline.	1/25/2008
EMSG America, Geological & Geophysical Prospecting for Mineral Resources, SEA T07–19.	Located in the western Gulf of Mexico south of Galveston, Texas.	1/31/2008
Apache Corporation, Structure Removal, SEA ES/SR 06–141A	West Cameron, Block 48, Lease OCS–G 00768, located 18 miles from the nearest Louisiana shoreline.	2/6/2008
Energy Resource Technology GOM, Inc., Structure Removal, SEA ES/SR 08–008.	South Timbalier (South Addition), Block 235, Lease OCS–G 14544, located 47 miles from the nearest Louisiana shoreline.	2/9/2008
Energy Resource Technology GOM, Inc., Structure Removal, SEA ES/SR 08–009.	West Cameron, Block 488, Lease OCS–G 23774, located 83 miles from the nearest Louisiana shoreline.	2/9/2008
Energy Resource Technology GOM, Inc., Structure Removal, SEA ES/SR 08–007.	West Cameron (South Addition), Block 472, Lease OCS–G 22557, located 83 miles from the nearest Louisiana shoreline.	2/11/2008
WesternGeco, LLC, Geological & Geophysical Prospecting for Mineral Resources, SEA L08–02.	Located in the central Gulf of Mexico south of Fourchon, Louisiana.	2/15/2008
SPN Resources, Structure Removal, SEA ES/SR 07–161, 07–162.	Mobile, Block 861, Lease OCS–G 05062 & Block 819, Lease OCS–G 10920, located 3 to 7 miles from the nearest Alabama shoreline.	2/15/2008
ATP Oil & Gas Corporation, Structure Removal, SEA ES/SR 07–145.	West Cameron, Block 284, Lease OCS–G 17776, located 20 miles from the nearest Louisiana shoreline.	2/15/2008
Devon Energy Production Company L.P., Structure Removal, SEA ES/SR 08–010.	Eugene Island, Block 120, Lease OCS–G 00050, located 21 miles from the nearest Louisiana shoreline.	2/22/2008
Chevron U.S.A., Inc., Structure Removal, SEA ES/SR 08–015 ..	South Marsh, Block 8, Lease OCS–G 03401, located 32 miles from the nearest Louisiana shoreline.	2/22/2008
Exxon Mobil Exploration Production Company, Geological & Geophysical Exploration for Mineral Resources, SEA L08–07.	Located in the central Gulf of Mexico 75 miles south of Lafourche Parish, Louisiana.	2/26/2008
Maritech Resources, Inc., Structure Removal, SEA ES/SR 99–121A.	West Cameron, Block 352, Lease OCS–G 02839, located 49 miles from the nearest Louisiana shoreline.	2/26/2008
TGS–NOPEC Geophysical Company L.P., Geological & Geophysical Prospecting for Mineral Resources, SEA L08–03.	Located in the central Gulf of Mexico south of Beaumont/Port Arthur, Texas.	2/29/2008
Western GECO, LLC, Geological & Geophysical Prospecting for Mineral Resources, SEA L08–08.	Located in the central Gulf of Mexico south of Venice, Louisiana.	2/29/2008
WesternGeco, LLC, Geological & Geophysical Prospecting for Mineral Resources, SEA T08–01.	Located in the western/central Gulf of Mexico south of Galveston, Texas.	2/29/2008
Hunt Oil Company, Structure Removal, SEA ES/SR 08–019	Ship Shoal, Block 37, Lease OCS–G 26049, located 8 miles from the nearest Louisiana shoreline.	3/4/2008
ATP Oil & Gas Corporation, Structure Removal, SEA ES/SR 08–001.	Ship Shoal, Block 105, Lease OCS–G 09614, located 33 miles from the nearest Louisiana shoreline.	3/6/2008
Maritech Resources, Inc., Structure Removal, SEA ES/SR 08–006.	Ship Shoal, Block 291, Lease OCS–G 02923, located 58 miles from the nearest Louisiana shoreline.	3/6/2008
Callon Petroleum Operating Company, Structure Removal, SEA ES/SR 08–020, 08–021.	South Marsh Island (North Addition), Block 260, Lease OCS–G 02305, located 27 miles from the nearest Louisiana shoreline.	3/6/2008
Walter Oil & Gas Corporation, Structure Removal, SEA ES/SR 02–098A.	Galveston, Block A218, Lease OCS–G 14152, located 74 miles from the nearest Texas shoreline.	3/6/2008

Activity/operator	Location	Date
CGG Veritas, Geological & Geophysical Prospecting for Mineral Resources, SEA L07–06.	Located in the central Gulf of Mexico south of Fourchon, Louisiana.	3/8/2008
LLOG Exploration Offshore, Inc., Structure Removal, SEA ES/SR 08–025.	East Cameron, Block 81, Lease OCS–G 01477, located 27 miles from the nearest Louisiana shoreline.	3/11/2008
Chevron U.S.A., Inc., Structure Removal, SEA ES/SR 08–024 ..	Eugene Island, Block 338, Lease OCS–G 02118, located 76 miles from the nearest Louisiana shoreline.	3/11/2008
Apache Corporation, Structure Removal, SEA ES/SR 07–155 ...	South Timbalier, Block 161, Lease OCS–G 01248, located 32 miles from the nearest Louisiana shoreline.	3/18/2008
Chevron U.S.A., Inc., Structure Removal, SEA ES/SR 08–023 ..	Vermilion, Block 245B, Lease OCS–G 01146, located 67 miles from the nearest Louisiana shoreline.	3/18/2008
Maritech Resources, Inc., Structure Removal, SEA ES/SR 06–163.	West Cameron (South Addition), Block 528, Lease OCS–G 16202, located 91 miles from the nearest Louisiana shoreline.	3/18/2008
W & T Offshore, Inc., Structure Removal, SEA ES/SR 08–016 ..	Main Pass, Block 141, Lease OCS–G 09710, located 17 miles from the nearest Louisiana shoreline.	3/19/2008
Petrobras America, Inc., Initial Development Operations Coordination Document, SEA N–9015.	Walker Ridge, Blocks 206, 249 & 425, Leases OCS–G 16965, 16969 & 16987 respectfully, located 165 miles to the nearest Louisiana shoreline.	3/20/2008
Millenium Offshore Group, Inc., on behalf of ATP Oil & Gas Corporation, Structure Removal, SEA ES/SR 08–041.	Eugene Island, Block 190, Lease OCS–G 08434, located 35 miles from the nearest Louisiana shoreline.	3/21/2008
McMoran Oil & Gas, LLC, Structure Removal, SEA ES/SR 08–029.	Eugene Island, Block 203, Lease OCS–G 22670, located 50 miles from the nearest Louisiana shoreline.	3/21/2008
Energy Resource Technology GOM, Inc., Structure Removal, SEA ES/SR 08–032, 08–033.	South Pelto, Block 20, Lease OCS 00074, located 7 miles from the nearest Louisiana shoreline.	3/24/2008
Apache Corporation, Structure Removal, SEA ES/SR 08–038, 08–039.	High Island, Block 169, Lease OCS–G 14161, located 30 miles from the nearest Texas shoreline.	3/24/2008
BP Exploration & Production, Inc., Revised Exploration Plan, SEA R–4803 AA.	Mississippi Canyon, Block 775, Lease OCS–G 19997, located 79 miles south of The Venice, Louisiana shoreline.	3/25/2008
Stone Energy Corporation, Initial Exploration Plan, SEA N–9106	Main Pass, Block 72, Lease OCS–G 03417, located 6 miles from the nearest Plaquemines Parish, Louisiana shoreline.	3/26/2008
Coastal Technology Corporation, Geological & Geophysical Prospecting for Mineral Resources, SEA E07–02.	Located off the coast of St. Lucie County, Florida on the Federal OCS of the Atlantic Ocean.	3/27/2008
GOM Shelf, LLC, Structure Removal, SEA ES/SR 08–040	Matagorda Island, Block 633, Lease OCS–G 06042, located 14 miles from the nearest Texas shoreline.	3/27/2008
Energy Resource Technology, Structure Removal, SEA ES/SR 08–030, 08–031.	South Pelto, Block 12, Lease OCS–G 00072, located 9 miles from the nearest Louisiana shoreline.	3/27/2008
Apache Corporation, Structure Removal, SEA ES/SR 07–148, 07–149, 07–150.	West Delta, Blocks 104 & 103, Leases OCS–G 00841 & 00840, located 27 miles from the nearest Louisiana shoreline.	3/21/2008

Persons interested in reviewing environmental documents for the proposals listed above or obtaining information about SEAs and FONSIs prepared for activities on the Gulf of Mexico OCS are encouraged to contact MMS at the address or telephone listed in the **FOR FURTHER INFORMATION CONTACT** section.

Dated: April 21, 2008.

Lars Herbst,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. E8–14655 Filed 6–26–08; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Notice on Outer Continental Shelf Oil and Gas Lease Sales

AGENCY: Minerals Management Service, Interior.

ACTION: Correction—List of Restricted Joint Bidders.

SUMMARY: On April 22, 2008, pursuant to the authority vested in the Director of the Minerals Management Service by the joint bidding provisions of 30 CFR 256.41, as a matter of information to the public, the MMS published in the **Federal Register** the current List of Restricted Bidders. Under this authority, MMS determined that each entity within one of the following groups is restricted from bidding with any entity in any other of the following groups at Outer Continental Shelf oil and gas lease sales to be held during the bidding period May 1, 2008 through October 31, 2008. We inadvertently omitted a new group, ''Group IX.,'' that shall be restricted from bidding with any entity in any other group of restricted bidders during this bidding period. The corrected List of Restricted Joint Bidders is provided below and is effective as of the date of the previous **Federal Register** publication, April 22, 2008.

Group I.
- Exxon Mobil Corporation
- ExxonMobil Exploration Company

Group II.
- Shell Oil Company
- Shell Offshore, Inc.
- SWEPI LP
- Shell Frontier Oil & Gas, Inc.
- Shell Consolidated Energy Resources, Inc.
- Shell Land & Energy Company
- Shell Onshore Ventures, Inc.
- Shell Offshore Properties and Capital II, Inc.
- Shell Rocky Mountain Production, LLC
- Shell Gulf of Mexico, Inc.

Group III.
- BP America Production Company
- BP Exploration & Production, Inc.
- BP Exploration (Alaska), Inc.

Group IV.
- TOTAL E&P USA, Inc.

Group V.
- Chevron Corporation
- Chevron U.S.A., Inc.
- Chevron Midcontinent, L.P.
- Unocal Corporation
- Union Oil Company of California
- Pure Partners, L.P.

Group VI.
- ConocoPhillips Company
- ConocoPhillips Alaska, Inc.
- ConocoPhillips Petroleum Company
- Phillips Pt. Arguello Production Company
- Burlington Resources Oil & Gas Company, LP
- Burlington Resources Offshore, Inc.
- The Louisiana Land and Exploration Company

Inexeco Oil Company

Group VII.
Eni Petroleum Co., Inc.
Eni Petroleum US, LLC
Eni Oil US, LLC
Eni Marketing, Inc.
Eni BB Petroleum, Inc.
Eni U.S. Operating Co., Inc.
Eni BB Pipeline, LLC

Group VIII.
Petrobras America, Inc.

Group IX.
StatoilHydro ASA
Statoil Gulf of Mexico, LLC
StatoilHydro USA E&P, Inc.
StatoilHydro Gulf Properties, Inc.

Dated: June 9, 2008.

Randall B. Luthi,

Director, Minerals Management Service.

[FR Doc. E8–14654 Filed 6–26–08; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–565]

In the Matter of: Certain Ink Cartridges and Components Thereof; Enforcement Proceeding II; Institution of Formal Enforcement Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has instituted a formal enforcement proceeding in the above-captioned investigation and named two enforcement respondents in the proceeding.

FOR FURTHER INFORMATION CONTACT: Michael Haldenstein, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3041. Copies of all nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov/*. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted the underlying investigation in this matter on March 23, 2006, based on a complaint filed by Epson Portland, Inc. of Oregon; Epson America, Inc. of California; and Seiko Epson Corporation of Japan (collectively ''Epson''). 71 FR. 14720 (March 23, 2006). The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930 (''section 337'') in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain ink cartridges and components thereof by reason of infringement of claim 7 of U.S. Patent No. 5,615,957; claims 18, 81, 93, 149, 164 and 165 of U.S. Patent No. 5,622,439; claims 83 and 84 of U.S. Patent No. 5,158,377; claims 19 and 20 of U.S. Patent No. 5,221,148; claims 29, 31, 34 and 38 of U.S. Patent No. 5,156,472; claim 1 of U.S. Patent No. 5,488,401; claims 1–3 and 9 of U.S. Patent No. 6,502,917; claims 1, 31 and 34 of U.S. Patent No. 6,550,902; claims 1, 10 and 14 of U.S. Patent No. 6,955,422; claim 1 of U.S. Patent No. 7,008,053; and claims 21, 45, 53 and 54 of U.S. Patent No. 7,011,397. The complaint further alleged that an industry in the United States exists as required by subsection (a)(2) of section 337. The complainants requested that the Commission issue a general exclusion order and cease and desist orders. The Commission named as respondents 24 companies located in China, Germany, Hong Kong, Korea, and the United States. Several respondents were terminated from the investigation on the basis of settlement agreements or consent orders or were found in default.

On March 30, 2007, the presiding administrative law judge (ALJ) issued a final ID in the investigation finding a violation of section 337 with respect to certain respondents. He found the asserted claims valid and infringed by certain respondents' products. He recommended issuance of a general exclusion order and cease and desist orders directed to certain respondents and bond in the amount of $13.60 per cartridge during the Presidential review period.

On October, 19, 2007, after review, the Commission made its final determination in the investigation, finding a violation of section 337. The Commission issued a general exclusion order, limited exclusion order, and cease and desist orders directed to several domestic respondents. The Commission also determined that the public interest factors enumerated in 19 U.S.C. 1337(d), (f), and (g) did not preclude issuance of the aforementioned remedial orders, and that the bond during the Presidential review period would be $13.60 per cartridge for covered ink cartridges.

On May 1, 2008, the Commission, based on two complaints filed by Epson on February 8, 2008, determined to institute a consolidated formal enforcement proceeding to determine whether certain respondents are in violation of the Commission's exclusion orders and cease and desist orders issued in the investigation, and what, if any, enforcement measures are appropriate. The following companies were named as respondents: Ninestar Technology Co., Ltd.; Ninestar Technology Company, Ltd.; Town Sky Inc.; Mipo America Ltd.; and Mipo International, Ltd.

Based upon a third complaint filed by Epson on March 18, 2008, alleging violations of the general exclusion order and a consent order, the Commission has now determined to institute another formal enforcement proceeding to determine whether two respondents are in violation of the Commission's general exclusion order and a consent order issued in the investigation, and what, if any, enforcement measures are appropriate. The following entities are named as parties to the formal enforcement proceeding: (1) Complainant Epson; (2) respondents Ribbon Tree USA, Inc. (dba Cana-Pacific Ribbons) and Apex Distributing Inc; and (3) a Commission investigative attorney to be designated by the Director, Office of Unfair Import Investigations.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.75 of the Commission's Rules of Practice and Procedure (19 CFR 210.75).

Issued: June 23, 2008.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–14632 Filed 6–26–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Verizon Communications Inc. and Rural Cellular Corporation; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)-(h), that a proposed Final Judgment, Stipulation, and

Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Verizon Communications Inc. and Rural Cellular Corporation,* Civil Action No. 08-cv-0993 (EGS). On June 10, 2008, the United States filed a Complaint alleging that the proposed acquisition by Verizon Communications Inc. (''Verizon'') of the wireless telecommunications services business of Rural Cellular Corporation (''RCC'') would violate Section 7 of the Clayton Act, 15 U.S.C. 18 by substantially lessening competition in the provision of mobile wireless telecommunications services in six (6) geographic areas. The proposed Final Judgment, filed the same time as the Complaint, requires the divestiture of RCC's mobile wireless telecommunications services businesses in the state of Vermont and in certain areas in the states of New York and Washington in order for Verizon to proceed with its $2.67 billion acquisition of RCC. The Competitive Impact Statement filed by the United States describes the Complaint, the proposed Final Judgment, the industry, and the remedies available to private litigants who may have been injured by the alleged violation.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection at the Department of Justice, Antitrust Division, Antitrust Documents Group, Suite 1010, Liberty Square Building, 450 5th Street, Washington, DC 20530 (telephone: 202–514–2481), on the Department of Justice's Web site at *http://www.usdoj.gov/atr,* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by the Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Nancy Goodman, Chief, Telecommunications and Media Enforcement Section, Antitrust Division, U.S. Department of Justice, 1401 H Street, NW., Suite 8000, Washington, DC 20530 (telephone: 202–514–5621).

J. Robert Kramer II,

Director of Operations, Antitrust Division.

In the United States District Court for the District of Columbia

United States Of America, Department of Justice, Antitrust Division, 1401 H Street, NW., Suite 8000, Washington, DC 20530, and State of Vermont, Office of the Vermont Attorney General, 109 State Street, Montpelier, Vermont 056091001, Plaintiffs, v. *Verizon Communications Inc., 140 West Street, New York, New York 1007, and Rural Cellular Corporation, 3905 Dakota Street SW., Alexandria, Minnesota 56308, Defendants.*

Civil No. 1:08–cv–00993(EGS).
Judge Emmet G. Sullivan.
Filed: June 10, 2008.

Complaint

The United States of America, acting under the direction of the Attorney General of the United States, and the State of Vermont, by its Attorney General William H. Sorrell, bring this civil action to enjoin the merger of two mobile wireless telecommunications services providers, Verizon Communications Inc. (''Verizon'') and Rural Cellular Corporation (''RCC''), and to obtain other relief as appropriate. Plaintiffs allege as follows:

1. Verizon entered into an agreement to acquire RCC, dated July 29, 2007, under which the two companies would combine their mobile wireless telecommunications services businesses (''Transaction Agreement''). Plaintiffs seek to enjoin this transaction because it likely will substantially lessen competition to provide mobile wireless telecommunications services in several geographic markets where Verizon and RCC are each other's most significant competitor.

2. Verizon's mobile wireless telecommunications services network covers 263 million people in 49 states and serves in excess of 65 million subscribers. RCC provides mobile wireless telecommunications services in 15 states and serves approximately 790,000 subscribers. The combination of Verizon and RCC likely will substantially lessen competition for mobile wireless telecommunications services throughout Vermont, one geographic area in New York that is contiguous to Vermont, and in northeast Washington, where both Verizon and RCC currently operate. As a result of the proposed acquisition, residents of these areas will likely face increased prices, diminished quality or quantity of services, and less investment in network improvements for these services.

I. Jurisdiction and Venue

3. This Complaint is filed by the United States under Section 15 of the Clayton Act, 15 U.S.C. 25, to prevent and restrain defendants from violating Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18. Plaintiff Vermont, by and through its Attorney General, brings this action in its sovereign capacity and as parens patriae on behalf of the citizens, general welfare, and economy of the State of Vermont under Section 16 of the Clayton Act, 15 U.S.C. 26, to prevent defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18.

4. Verizon and RCC are engaged in interstate commerce and in activities substantially affecting interstate commerce. The Court has jurisdiction over this action pursuant to Sections 15 and 16 of the Clayton Act, 15 U.S.C. 25 and 26, and 28 U.S.C. 1331 and 1337.

5. The defendants have consented to personal jurisdiction and venue in this judicial district.

II. The Defendants and the Transaction

6. Verizon, with headquarters in New York, is a corporation organized and existing under the laws of the State of Delaware. Verizon is one of the world's largest providers of communications services. Verizon is the second largest mobile wireless telecommunications services provider in the United States as measured by subscribers, provides mobile wireless telecommunications services in 49 states, and serves in excess of 65 million subscribers. In 2007, Verizon earned mobile wireless telecommunications services revenues of approximately $43 billion.

7. RCC, with headquarters in Alexandria, Minnesota, is a corporation organized and existing under the laws of the State of Minnesota. RCC is the 10th largest mobile wireless telecommunications services provider in the United States as measured by subscribers, and provides mobile wireless telecommunications services in 15 states. It has approximately 790,000 subscribers. In 2007, RCC earned approximately $635.3 million in revenues.

8. Pursuant to an Agreement and Plan of Merger dated July 29, 2007, Verizon will acquire RCC for approximately $267 billion. If this transaction is consummated, Verizon and RCC combined would have approximately 66 million subscribers in the United States, with $44 billion in mobile wireless telecommunications services revenues.

III. Trade and Commerce

A. Nature of Trade and Commerce

9. Mobile wireless telecommunications services allow customers to make and receive telephone calls and obtain data services using radio transmissions without being confined to a small area during the call or data session, and without the need for unobstructed line-of-sight to the radio tower. Mobility is highly valued by customers, as demonstrated by the more than 255 million people in the United States who own mobile wireless telephones. In 2007, revenues from the sale of mobile wireless telecommunications services in the United States were over $138 billion. To meet this desire for mobility, mobile wireless telecommunications services providers must deploy extensive networks of switches and radio transmitters and receivers and interconnect their networks with the networks of wireline earners and other mobile wireless telecommunications services providers.

10. In the early to mid-1980s, the FCC issued two cellular licenses (A-block and B-block) in each Metropolitan Statistical Area (''MSA'') and Rural Service Area (''RSA'') (collectively, ''Cellular Marketing Areas'' or ''CMAs''), with a total of 734 CMAs covering the entire United States. Each license consists of 25 MHz of spectrum in the 800 MHz band. The first mobile wireless voice systems using this cellular spectrum were based on analog technology, now referred to as first-generation or ''1 G'' technology.

11. In 1995, the FCC licensed additional spectrum for the provision of Personal Communications Services (''PCS''), a category of services that includes mobile wireless telecommunications services comparable to those offered by cellular licensees. These licenses are in the 1900 MHz band and are divided into six blocks: A, B, and C, which consist of 30 MHz each; and D, E, and F, which consist of 10 MHz each. Geographically, the A and B-block 30 MHz licenses are issued by Major Trading Areas (''MTAs''). C, D, E, and F-block licenses are issued by Basic Trading Areas (''BTAs''), several of which comprise each MTA. MTAs and BTAs do not generally correspond to MSAs and RSAs.

12. With the introduction of the PCS licenses, both cellular and PCS licensees began offering digital services, thereby increasing network capacity, shrinking handsets, and extending battery life. In addition, in 1996, one provider, a specialized mobile radio (''SMR'' or ''dispatch'') spectrum licensee, began to use its SMR spectrum to offer mobile wireless telecommunications services comparable to those offered by other mobile wireless telecommunications services providers, in conjunction with its dispatch, or ''push-to-talk,'' service. Although there are a number of providers holding spectrum licenses in each area of the country, not all providers have fully built out their networks throughout each license area. In particular, because of the characteristics of PCS spectrum, providers holding this type of spectrum generally have found it less attractive to build out in rural areas.

13. Today, more than 95 percent of the total U.S. population lives in counties where three or more mobile wireless telecommunications services operators offer service. Nearly all mobile wireless voice services have migrated to second-generation or ''2G'' digital technologies, GSM (global standard for mobility), and CDMA (code division multiple access). Even more advanced technologies (''2.5G'' and ''3G''), based on the earlier 2G technologies, have been deployed for mobile wireless data services.

B. Relevant Product Market

14. Mobile wireless telecommunications services is a relevant product market. Mobile wireless telecommunications services include both voice and data services provided over a radio network and allow customers to maintain their telephone calls or data sessions without wires when traveling. There are no cost-effective alternatives to mobile wireless telecommunications services. Because fixed wireless services are not mobile, they are not regarded by consumers of mobile wireless telecommunications services to be a reasonable substitute for those services. It is unlikely that a sufficient number of customers would switch away from mobile wireless telecommunications services to make a small but significant price increase in those services unprofitable. Mobile wireless telecommunications services accordingly is a relevant product market under Section 7 of the Clayton Act, 15 U.S.C. 18.

C. Relevant Geographic Markets

15. The United States comprises numerous local geographic markets for mobile wireless telecommunications services. A large majority of customers use mobile wireless telecommunications services in close proximity to their workplaces and homes. Thus, customers purchasing mobile wireless telecommunications services choose among mobile wireless telecommunications services providers that offer services where they live, work, and travel on a regular basis. The geographic areas in which the FCC has licensed mobile wireless telecommunications services providers often represent the core of the business and social sphere within which customers have the same competitive choices for mobile wireless telephone services. The number and identity of mobile wireless telecommunications services providers varies among geographic areas, as does the quality of services and breadth of geographic coverage offered by providers. Some mobile wireless telecommunications services providers can and do offer different promotions, discounts, calling plans, and equipment subsidies in different geographic areas, varying the price for customers by geographic area.

16. The relevant geographic markets, under Section 7 of the Clayton Act, 15 U.S.C. 18, where the transaction will substantially lessen competition for mobile wireless telecommunications services are effectively represented by the following FCC spectrum licensing areas: Burlington, Vermont (CMA 248); New York RSA–2 (CMA 560); Vermont RSA–1 (CMA 679); Vermont RSA–2 (CMA 680); Washington RSA–2 (CMA 694); and Washington RSA–3 (CMA 695). It is unlikely that a sufficient number of customers would switch to mobile wireless telecommunications services providers who do not offer services in these geographic areas to make a small but significant price increase in the relevant geographic markets unprofitable.

D. Anticompetitive Effects

1. Mobile Wireless Telecommunications Services

17. In each of the cellular license areas described above, Verizon and RCC are the two largest carriers (based on subscribers), with a combined share in each area ranging from over 60% to nearly 94%, and are each other's closest competitor for a significant set of customers. In all but a portion of one of these cellular license areas, Verizon and RCC hold all of the cellular spectrum licenses.

18. The relevant geographic markets for mobile wireless services are highly concentrated. As measured by the Herfindahl-Hirschman Index (''Hill''), which is commonly employed in merger analysis and is defined and explained in Appendix A to this Complaint, concentration in these geographic areas ranges from over 2800 to more than 5100, which is well above the 1800

threshold at which plaintiffs consider a market to be highly concentrated. After Verizon's proposed acquisition of RCC is consummated, the HHIs in the relevant geographic areas will range from over 4900 to over 8700, with increases in the HHI as a result of the merger ranging from over 1200 to over 4200, significantly beyond the thresholds at which plaintiffs consider a transaction likely to cause competitive harm.

19. Competition between Verizon and RCC in the relevant geographic markets has resulted in lower prices and higher quality in mobile wireless telecommunications services than would otherwise have existed in these geographic markets. In these areas, consumers consider Verizon and RCC to be particularly attractive competitors because other providers' networks lack coverage or provide lower-quality service. If Verizon's proposed acquisition of RCC is consummated, competition between Verizon and RCC in mobile wireless telecommunications services will be eliminated in these markets and the relevant markets for mobile wireless telecommunications services will become substantially more concentrated. As a result, the loss of competition between Verizon and RCC increases the merged firm's incentive and ability in the relevant geographic markets to increase prices, diminish the quality or quantity of services provided, and refrain from or delay making investments in network improvements.

2. Entry

20. Entry by a new mobile wireless services provider in the relevant geographic markets would be difficult, time-consuming, and expensive, requiring spectrum licenses and the build out of a network. Therefore, any entry in response to a small but significant price increase for mobile wireless telecommunications services by the merged firm in the relevant geographic markets would not be timely, likely, or sufficient to thwart the competitive harm resulting from Verizon's proposed acquisition of RCC, if it were to be consummated.

IV. Violation Alleged

21. The effect of Verizon's proposed acquisition of RCC, if it were to be consummated, may be substantially to lessen competition in interstate trade and commerce in the relevant geographic markets for mobile wireless telecommunications services, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

22. Unless restrained, the transaction will likely have the following effects in mobile wireless telecommunications services in the relevant geographic markets, among others:

a. Actual and potential competition between Verizon and RCC will be eliminated;

b. competition in general will be lessened substantially;

c. prices are likely to increase;

d. the quality and quantity of services are likely to decrease; and

e. incentives to improve wireless networks will be reduced.

V. Requested Relief

The plaintiffs request:

23. That Verizon's proposed acquisition of RCC be adjudged to violate Section 7 of the Clayton Act, 15 U.S.C. 18;

24. That defendants be permanently enjoined from and restrained from carrying out the Agreement and Plan of Merger dated July 29, 2007, or from entering into or carrying out any agreement, understanding, or plan, the effect of which would be to bring the wireless services businesses of Verizon and RCC under common ownership or control;

25. That plaintiffs be awarded their costs of this action; and

26. That plaintiffs have such other relief as the Court may deem just and proper.

Dated:

Respectfully Submitted,

For Plaintiff United States of America:

Thomas O. Barnett,
Assistant Attorney General, Antitrust Division;

Nancy Goodman,
Chief, Telecommunications & Media Enforcement Section, Antitrust Division;

Deborah A. Garza,
Deputy Assistant Attorney General, Antitrust Division;

Laury Bobbish,
Assistant Chief, Telecommunications & Media Enforcement Section, Antitrust Division;

Patricia A. Brink,
Deputy Director of Operations, Antitrust Division;

Hillary B. Burchuk (DC Bar No. 366755), Lawrence M. Frankel (DC Bar No. 441532), Jared A. Hughes, Deborah Roy (DC Bar No. 452573),

Attorneys, Telecommunications & Media Enforcement Section, Antitrust Division, U.S. Department of Justice, City Center Building, 1401 H Street, NW., Suite 8000, Washington, DC 20530, Phone: (202) 514–5621 Facsimile: (202) 514–6381.

For Plaintiff State of Vermont:

William H. Sorrell,
Vermont Attorney General;

Julie Brill,
Assistant Attorney General and Director, Antitrust;

Jennifer Giaimo,
Assistant Attorney General,

Office of the Vermont Attorney General, 109 State Street, Montpelier, Vermont 05609–1001, (802) 828–3658, Facsimile: (802) 828–2154.

Appendix A

Herfindahl-Hirschman Index

''HHI'' means the Herfindahl-Hirschman Index, a commonly accepted measure of market concentration. It is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2600 ($30^2 + 30^2 + 20^2 + 20^2 = 2600$). (Note: Throughout the Complaint, market share percentages have been rounded to the nearest whole number, but HHIs have been estimated using unrounded percentages in order to accurately reflect the concentration of the various markets.) The HHI takes into account the relative size distribution of the firms in a market and approaches zero when a market consists of a large number of small firms. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases.

Markets in which the HHI is between 1000 and 1800 points are considered to be moderately concentrated, and those in which the HHI is in excess of 1800 points are considered to be highly concentrated. *See Horizontal Merger Guidelines* ¶ 1.51 (revised Apr. 8, 1997). Transactions that increase the HHI by more than 100 points in concentrated markets presumptively raise antitrust concerns under the guidelines issued by the U.S. Department of Justice and Federal Trade Commission. *See id.*

In the United States District Court for the District of Columbia

United States of America and State of Vermont, Plaintiffs, v. *Verizon Communications Inc. and Rural Cellular Corporation, Defendants.*
Case No. 1:08–cv–00993(EGS).
Judge Emmet G. Sullivan.
Filed: June 10, 2008.

Final Judgment

Whereas, plaintiffs, United States of America and the State of Vermont, filed their Complaint on June 10, 2008, plaintiffs and defendants, Verizon Communications Inc. (''Verizon'') and Rural Cellular Corporation (''RCC''), by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

And whereas, defendants agree to be bound by the provisions of this Final Judgment pending its approval by the Court;

And whereas, the essence of this Final Judgment is the prompt and certain divestiture of certain rights or assets by defendants to assure that competition is not substantially lessened;

And whereas, plaintiffs require defendants to make certain divestitures for the purpose of remedying the loss of competition alleged in the Complaint;

And whereas, defendants have represented to plaintiffs that the divestitures required below can and will be made and that defendants will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the divestiture provisions contained below;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is *ordered, adjudged and decreed*:

I. Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against defendants under Section 7 of the Clayton Act, as amended (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. ''Acquirer'' or ''Acquirers'' means the entity or entities to whom defendants divest the Divestiture Assets.

B. ''CMA'' means cellular market area which is used by the Federal Communications Commission (''FCC'') to define cellular license areas and which consists of Metropolitan Statistical Areas (''MSAs'') and Rural Service Areas (''RSAs'')

C. ''Divestiture Assets'' means each mobile wireless telecommunications services business to be divested under this Final Judgment, including all types of assets, tangible and intangible, used by defendants in the operation of the mobile wireless telecommunications services businesses to be divested. ''Divestiture Assets'' shall be construed broadly to accomplish the complete divestiture of the entire business of RCC in each of the following CMA license areas as required by this Final Judgment and to ensure that the divested mobile wireless telecommunications services businesses remain viable, ongoing businesses:

(1) Burlington, VT MSA (CMA 248);
(2) New York RSA 2 (CMA 560);
(3) Vermont RSA 1 (CMA 679);
(4) Vermont RSA 2 (CMA 680);
(5) Washington RSA 2 (CMA 694); and
(6) Washington RSA 3 (CMA 695);

provided that defendants may retain all of the PCS spectrum licenses RCC currently holds in each of these CMAs, except in the Burlington MSA, and equipment that is used only for wireless transmissions over this PCS spectrum. Defendants may also retain the Ericsson AXE 810 switch located in Colchester, VT used to support the GSM mobile wireless telecommunications services currently provided by RCC; the Lucent 5E switch located in Colchester, VT used to support CDMA, TDMA and analog mobile wireless telecommunications services currently provided by RCC; the CDMA, TDMA and analog equipment on the radio tower located at Woodstock (latitude 43.613975, longitude -72.52175) and any associated rights for this equipment to remain on this tower currently owned and held by RCC; and the CDMA equipment located on the radio tower located at Stratton (latitude 43.11344, longitude -72.90691) and any associated rights for this equipment to remain on this tower currently owned and held by RCC. In addition, defendants also (i) may retain in the Burlington MSA, RCC's PCS spectrum license, and (ii) in the Vermont RSA 2–B2 service area, which includes Bennington and Windham counties, and the portion of Windsor county south of U.S. Route 4, may substitute a license for 10 MHz of RCC's cellular spectrum for RCC's 10 MHz PCS spectrum license, if approved by plaintiff United States in its sole discretion, upon consultation with plaintiff Vermont.

The Divestiture Assets shall include, without limitation, all types of real and personal property, monies and financial instruments, equipment, inventory, office furniture, fixed assets and furnishings, supplies and materials, contracts, agreements, leases, commitments, spectrum licenses issued by the FCC and all other licenses, permits and authorizations, operational support systems, cell sites, network infrastructure, switches, customer support and billing systems, interfaces with other service providers, business and customer records and information, customer contracts, customer lists, credit records, accounts, and historic and current business plans that relate primarily to the wireless businesses being divested, as well as any patents, licenses, sub-licenses, trade secrets, know-how, drawings, blueprints, designs, technical and quality specifications and protocols, quality assurance and control procedures, manuals and other technical information defendant RCC supplies to its own employees, customers, suppliers, agents, or licensees, and trademarks, trade names and service marks or other intellectual property, including all intellectual property rights under third-party licenses that are capable of being transferred to the Acquirer(s) either in their entirety, for assets described in (a) below, or through a license obtained through or from RCC, for assets described in (b) below; provided that defendants shall only be required to divest Multi-line Business Customer contracts if the primary business address for that customer is located within any of the six license areas described herein, and further, any subscriber who obtains mobile wireless telecommunications services through any such contract retained by defendants and who are located within the six license areas identified above, shall be given the option to terminate their relationship with defendants, without financial cost, at any time within one year of the closing of the Transaction. Defendants shall provide written notice to these subscribers within 45 days after the closing of the Transaction of the option to terminate.

The divestiture of the Divestiture Assets shall be accomplished by:

(a) transferring to the Acquirer(s) the complete ownership and/or other rights to the assets (other than those assets used substantially in the operations of RCC's overall wireless telecommunications services business that must be retained to continue the existing operations of the wireless properties that defendants are not required to divest, and that either are not capable of being divided between the divested wireless telecommunications services businesses and those not divested, or are assets that the defendants and the Acquirer(s) agree, subject to the approval of plaintiff United States, shall not be divided); and

(b) granting to the Acquirer(s) an option to obtain a nonexclusive, transferable license from defendants for a reasonable period, subject to the approval of plaintiff United States, and at the election of the Acquirer(s), to use any of RCC's retained assets under paragraph (a) above used in operating the mobile wireless telecommunications services businesses being divested, so as to enable the Acquirer(s) to continue to operate the divested mobile wireless telecommunications services businesses without impairment. Defendants shall identify in a schedule submitted to plaintiff United States and filed with the Court as expeditiously as possible following the filing of the Complaint, and in any event prior to any divestiture and before the approval by the Court of this Final Judgment, any and all intellectual property rights under third-party licenses that are used by the mobile wireless telecommunications services businesses being divested that defendants could not transfer to the Acquirer(s) entirely or by license without third-party consent, the specific reasons why such consent is necessary, and how such consent would be obtained for each asset.

D. ''Multi-line Business Customer'' means a corporate or business customer that contracts with RCC for mobile wireless telecommunications services to provide multiple telephones to its employees or members whose services are provided pursuant to a contract with the corporate or business customer.

E. ''RCC'' means defendant Rural Cellular Corporation, a Minnesota corporation with its headquarters in Alexandria, Minnesota, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

F. ''Transaction'' means the Agreement and Plan of Merger, dated July 29, 2007.

G. ''Verizon'' means defendant Verizon Communications Inc., a Delaware corporation, with its headquarters in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

III. Applicability

A. This Final Judgment applies to defendants Verizon and RCC, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

B. If, prior to complying with Section IV and V of this Final Judgment, Defendants sell or otherwise dispose of all or substantially all of their assets or of lesser business units that

include the Divestiture Assets, they shall require the purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from the acquirer(s) of the assets divested pursuant to this Final Judgment.

IV. Divestitures

A. Defendants are ordered and directed, within 120 days after consummation of the Transaction, or five (5) calendar days after notice of the entry of this Final Judgment by the Court, whichever is later, to divest the Divestiture Assets in a manner consistent with this Final Judgment to an Acquirer or Acquirers acceptable to plaintiff United States in its sole discretion, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, or, if applicable, to a Divestiture Trustee designated pursuant to Section V of this Final Judgment. Plaintiff United States, in its sole discretion, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, may agree to one or more extensions of this time period not to exceed 60 calendar days in total, and shall notify the Court in such circumstances. With respect to divestiture of the Divestiture Assets by defendants or the Divestiture Trustee, if applications have been filed or are on file with the FCC within the period permitted for divestiture seeking approval to assign or transfer licenses to the Acquirer(s) of the Divestiture Assets, but an order or other dispositive action by the FCC on such applications has not been issued before the end of the period permitted for divestiture, the period shall be extended with respect to divestiture of those Divestiture Assets for which FCC approval has not been issued until five (5) days after such approval is received. Defendants agree to use their best efforts to accomplish the divestitures set forth in this Final Judgment and to seek all necessary regulatory approvals as expeditiously as possible. This Final Judgment does not limit the FCC's exercise of its regulatory powers and process with respect to the Divestiture Assets. Authorization by the FCC to conduct the divestiture of a Divestiture Asset in a particular manner will not modify any of the requirements of this decree.

B. In accomplishing the divestitures ordered by this Final Judgment, defendants shall promptly make known, if they have not already done so, by usual and customary means, the availability of the Divestiture Assets. Defendants shall inform any person making inquiry regarding a possible purchase of the Divestiture Assets that they are being divested pursuant to this Final Judgment and provide that person with a copy of this Final Judgment. Defendants shall offer to furnish to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets customarily provided in a due diligence process except such information or documents subject to the attorney-client or work product privileges. Defendants shall make available such information to plaintiffs at the same time that such information is made available to any other person. Notwithstanding the provisions of this paragraph, with the consent of plaintiff United States in its sole discretion, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, the defendants may enter into exclusive negotiations to sell the Divestiture Assets and may limit their obligations under this paragraph to the provision of information to a single potential buyer for the duration of those negotiations.

C. Defendants shall provide the Acquirer(s) and plaintiffs information relating to the personnel involved in the operation, development, and sale or license of the Divestiture Assets to enable the Acquirer(s) to make offers of employment. Defendants will not interfere with any negotiations by the Acquirer(s) to employ any defendant employee whose primary responsibility is the operation, development, or sale or license of the Divestiture Assets.

D. Defendants shall permit prospective Acquirers of the Divestiture Assets to have reasonable access to personnel and to make inspections of the Divestiture Assets; access to any and all environmental, zoning, and other permit documents and information; and access to any and all financial, operational, and other documents and information customarily provided as part of a due diligence process.

E. Defendants shall warrant to the Acquirer(s) that (1) the Divestiture Assets will be operational on the date of sale, and (2) every wireless spectrum license is in full force and effect on the date of sale.

F. Defendants shall not take any action that will impede in any way the permitting, licensing, operation, or divestiture of the Divestiture Assets.

G. Defendants shall warrant to the Acquirer(s) of the Divestiture Assets that there are no material defects in the environmental, zoning, licensing or other permits pertaining to the operation of each asset and that following the sale of the Divestiture Assets, defendants will not undertake, directly or indirectly, any challenges to the environmental, zoning, licensing or other permits relating to the operation of the Divestiture Assets.

H. Unless plaintiff United States, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, otherwise consents in writing, the divestitures pursuant to Section IV, or by a Divestiture Trustee appointed pursuant to Section V, of this Final Judgment, shall include the entire Divestiture Assets, and shall be accomplished in such a way as to satisfy plaintiff United States in its sole discretion that these assets can and will be used by the Acquirer(s) as part of a viable, ongoing business engaged in the provision of mobile wireless telecommunications services. The Divestiture Assets in Vermont and New York shall all be divested to a single Acquirer and the Divestiture Assets in Washington shall all be divested to a single Acquirer, provided that it is demonstrated to the sole satisfaction of plaintiff United States, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, that the Divestiture Assets will remain viable and the divestiture of such assets will remedy the competitive harm alleged in the Complaint. The divestiture of the Divestiture Assets, whether pursuant to Section IV or Section V of this Final Judgment,

(1) shall be made to an Acquirer or Acquirers that, in plaintiff United States's sole judgment, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, has the intent and capability (including the necessary managerial, operational, technical, and financial capability) of competing effectively in the provision of mobile wireless telecommunications services; and

(2) shall be accomplished so as to satisfy plaintiff United States in its sole discretion, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, that none of the terms of any agreement between an Acquirer(s) and defendants shall give defendants the ability unreasonably to raise the Acquirer's costs, to lower the Acquirer's efficiency, or otherwise to interfere with the ability of the Acquirer to compete effectively.

I. At the option of the Acquirer(s) of the Divestiture Assets, defendants shall enter into a contract for transition services customarily provided in connection with the sale of a business providing mobile wireless telecommunications services or intellectual property licensing sufficient to meet all or part of the needs of the Acquirer(s) for a period of up to one year. The terms and conditions of any contractual arrangement meant to satisfy this provision must be reasonably related to market conditions.

J. To the extent that the Divestiture Assets use intellectual property, as required to be identified by Section II.C, that cannot be transferred or assigned without the consent of the licensor or other third parties, defendants shall use their best efforts to obtain those consents.

V. Appointment of Divestiture Trustee

A. If defendants have not divested the Divestiture Assets within the time period specified in Section IV.A, defendants shall notify plaintiff United States, and with respect to the Divestiture Assets located in Vermont notify plaintiff Vermont of that fact in writing, specifically identifying the Divestiture Assets that have not been divested. Upon application of plaintiff United States, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, the Court shall appoint a Divestiture Trustee selected by plaintiff United States and approved by the Court to effect the divestiture of the Divestiture Assets. The Divestiture Trustee will have all the rights and responsibilities of the Management Trustee who may be appointed pursuant to the Preservation of Assets Stipulation and Order, and will be responsible for:

(1) accomplishing divestiture of all Divestiture Assets transferred to the Divestiture Trustee from defendants, in accordance with the terms of this Final Judgment, to an Acquirer(s) approved by plaintiff United States, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, under Section IV.A of this Final Judgment; and

(2) exercising the responsibilities of the licensee of any transferred Divestiture Assets and controlling and operating any transferred Divestiture Assets, to ensure that the businesses remain ongoing, economically viable competitors in the provision of mobile wireless telecommunications services in the license areas specified in Section II.C, until they are divested to an Acquirer(s), and the Divestiture Trustee shall agree to be bound by this Final Judgment.

B. Defendants shall submit a proposed trust agreement (''Trust Agreement'') to plaintiff United States, which must be consistent with the terms of this Final Judgment and which must receive approval by plaintiff United States in its sole discretion, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, who shall communicate to defendants within 10 business days its approval or disapproval of the proposed Trust Agreement, and which must be executed by the defendants and the Divestiture Trustee within five business days after approval by plaintiff United States.

C. After obtaining any necessary approvals from the FCC for the assignment of the licenses of the Divestiture Assets to the Divestiture Trustee, defendants shall irrevocably divest the remaining Divestiture Assets to the Divestiture Trustee, who will own such assets (or own the stock of the entity owning such assets, if divestiture is to be effected by the creation of such an entity for sale to Acquirer) and control such assets, subject to the terms of the approved Trust Agreement.

D. After the appointment of a Divestiture Trustee becomes effective, only the Divestiture Trustee shall have the right to sell the Divestiture Assets. The Divestiture Trustee shall have the power and authority to accomplish the divestiture to an Acquirer(s) acceptable to plaintiff United States, in its sole judgment, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, at such price and on such terms as are then obtainable upon reasonable effort by the Divestiture Trustee, subject to the provisions of Sections IV, V, and VI of this Final Judgment, and shall have such other powers as this Court deems appropriate. Subject to Section V.G of this Final Judgment, the Divestiture Trustee may hire at the cost and expense of defendants the Management Trustee appointed pursuant to the Preservation of Assets Stipulation and Order and any investment bankers, attorneys or other agents, who shall be solely accountable to the Divestiture Trustee, reasonably necessary in the Divestiture Trustee's judgment to assist in the divestiture.

E. In addition, notwithstanding any provision to the contrary, plaintiff United States, in its sole discretion, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, may require defendants to include additional assets, or with the written approval of plaintiff United States, allow defendants to substitute substantially similar assets, which substantially relate to the Divestiture Assets to be divested by the Divestiture Trustee to facilitate prompt divestiture to an acceptable Acquirer(s).

F. Defendants shall not object to a sale by the Divestiture Trustee on any ground other than the Divestiture Trustee's malfeasance. Any such objections by defendants must be conveyed in writing to plaintiff United States and the Divestiture Trustee within 10 calendar days after the Divestiture Trustee has provided the notice required under Section VI.

G. The Divestiture Trustee shall serve at the cost and expense of defendants, on such terms and conditions as plaintiff United States approves, and shall account for all monies derived from the sale of the assets sold by the Divestiture Trustee and all costs and expenses so incurred. After approval by the Court of the Divestiture Trustee's accounting, including fees for its services and those of any professionals and agents retained by the Divestiture Trustee, all remaining money shall be paid to defendants and the trust shall then be terminated. The compensation of the Divestiture Trustee and any professionals and agents retained by the Divestiture Trustee shall be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement providing the Divestiture Trustee with an incentive based on the price and terms of the divestiture, and the speed with which it is accomplished, but timeliness is paramount.

H. Defendants shall use their best efforts to assist the Divestiture Trustee in accomplishing the required divestitures, including their best efforts to effect all necessary regulatory approvals. The Divestiture Trustee and any consultants, accountants, attorneys, and other persons retained by the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities of the businesses to be divested, and defendants shall develop financial and other information relevant to the assets to be divested as the Divestiture Trustee may reasonably request, subject to reasonable protection for trade secret or other confidential research, development, or commercial information. Defendants shall take no action to interfere with or to impede the Divestiture Trustee's accomplishment of the divestitures.

I. After its appointment, the Divestiture Trustee shall file monthly reports with plaintiff United States, and with respect to the Divestiture Assets located in Vermont with plaintiff Vermont, and the Court setting forth the Divestiture Trustee's efforts to accomplish the divestitures ordered under this Final Judgment. To the extent such reports contain information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court. Such reports shall include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person. The Divestiture Trustee shall maintain full records of all efforts made to divest the Divestiture Assets.

J. If the Divestiture Trustee has not accomplished the divestitures ordered under the Final Judgment within six months after its appointment, the Divestiture Trustee shall promptly file with the Court a report setting forth (1) The Divestiture Trustee's efforts to accomplish the required divestitures, (2) the reasons, in the Divestiture Trustee's judgment, why the required divestitures have not been accomplished, and (3) the Divestiture Trustee's recommendations. To the extent such reports contain information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court The Divestiture Trustee shall at the same time furnish such report to plaintiff United States, and with respect to the Divestiture Assets located in Vermont to plaintiff Vermont, who shall have the right to make additional recommendations consistent with the purpose of the trust. The Court thereafter shall enter such orders as it shall deem appropriate to carry out the purpose of the Final Judgment, which may, if necessary, include extending the trust and the term of the Divestiture Trustee's appointment by a period requested by plaintiff United States, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont.

K. After defendants transfer the Divestiture Assets to the Divestiture Trustee, and until those Divestiture Assets have been divested to an Acquirer or Acquirers approved by plaintiff United States pursuant to Sections IV.A and IV.H, the Divestiture Trustee shall have sole and complete authority to manage and operate the Divestiture Assets and to exercise the responsibilities of the licensee and shall not be subject to any control or direction by defendants. Defendants shall not use, or retain any economic interest in, the Divestiture Assets transferred to the Divestiture Trustee, apart from the right to receive the proceeds of the sale or other disposition of the Divestiture Assets.

L. The Divestiture Trustee shall operate the Divestiture Assets consistent with the Preservation of Assets Stipulation and Order and this Final Judgment, with control over operations, marketing, and sales. Defendants shall not attempt to influence the business decisions of the Divestiture Trustee concerning the operation and management of the Divestiture Assets, and shall not communicate with the Divestiture Trustee concerning divestiture of the Divestiture Assets or take any action to influence, interfere with, or impede the Divestiture Trustee's accomplishment of the divestitures required by this Final Judgment, except that defendants may communicate with the Divestiture Trustee to the extent necessary for defendants to comply with this Final Judgment and to provide the Divestiture Trustee, if requested to do so, with whatever resources or cooperation may be required to complete divestiture of the Divestiture Assets and to carry out the requirements of the Preservation of Assets Stipulation and Order and this Final Judgment. Except as provided in this Final Judgment and the Preservation of Assets Stipulation and Order, in no event shall defendants provide to, or receive from, the Divestiture Trustee or the mobile wireless telecommunications services businesses any non-public or competitively sensitive

marketing, sales, pricing or other information relating to their respective mobile wireless telecommunications services businesses.

VI. Notice of Proposed Divestitures

A. Within the later of two (2) business days following (i) the execution of a definitive divestiture agreement, or (ii) the filing of the Complaint in this action, defendants or the Divestiture Trustee, whichever is then responsible for effecting the divestitures required herein, shall notify plaintiff United States, and with respect to the Divestiture Assets located in Vermont defendants shall notify plaintiff Vermont, in writing of any proposed divestiture required by Section IV or V of this Final Judgment. If the Divestiture Trustee is responsible, it shall similarly notify defendants. The notice shall set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets, together with full details of the same.

B. Within fifteen (15) calendar days of receipt of notice by plaintiff United States and plaintiff Vermont, if notice was given to plaintiff Vermont, plaintiff United States and plaintiff Vermont if it received notice, may request from defendants, the proposed Acquirer, any other third party, or the Divestiture Trustee, if applicable, additional information concerning the proposed divestiture, the proposed Acquirer, and any other potential Acquirer. Defendants and the Divestiture Trustee shall furnish any additional information requested within fifteen (15) calendar days of the receipt of the request, unless the parties shall otherwise agree.

C. Within thirty (30) calendar days after receipt of the notice or within twenty (20) calendar days after plaintiff United States and plaintiff Vermont have been provided the additional information requested from defendants, the proposed Acquirer, any third party, and the Divestiture Trustee, whichever is later, plaintiff United States, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, shall provide written notice to defendants and the Divestiture Trustee, if there is one, stating whether or not it objects to the proposed divestiture. If plaintiff United States provides written notice that it does not object, the divestiture may be consummated, subject only to defendants' limited right to object to the sale under Section V.F of this Final Judgment. Absent written notice that plaintiff United States does not object to the proposed Acquirer or upon objection by plaintiff United States, a divestiture proposed under Section IV or Section V shall not be consummated. Upon objection by defendants under Section V.F, a divestiture proposed under Section V shall not be consummated unless approved by the Court.

VII. Financing

Defendants shall not finance all or any part of any divestiture made pursuant to Section IV or V of this Final Judgment.

VIII. Preservation of Assets

Until the divestitures required by this Final Judgment have been accomplished, defendants shall take all steps necessary to comply with the Preservation of Assets Stipulation and Order entered by this Court and cease use of the Divestiture Assets during the period that the Divestiture Assets are managed by the Management Trustee. Defendants shall take no action that would jeopardize the divestitures ordered by this Court.

IX. Affidavits

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestitures have been completed under Section IV or V, defendants shall deliver to plaintiffs an affidavit as to the fact and manner of its compliance with Section IV or V of this Final Judgment. Each such affidavit shall include the name, address, and telephone number of each person who during the preceding thirty (30) calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person during that period. Each such affidavit shall also include a description of the efforts defendants have taken to solicit buyers for the Divestiture Assets, and to provide required information to prospective Acquirers, including the limitations, if any, on such information. Assuming the information set forth in the affidavit is true and complete, any objection by plaintiff United States, and with respect to Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, to information provided by defendants, including limitation on information, shall be made within fourteen (14) calendar days of receipt of such affidavit.

B. Within twenty (20) calendar days of the filing of the Complaint in this matter, defendants shall deliver to plaintiffs an affidavit that describes in reasonable detail all actions defendants have taken and all steps defendants have implemented on an ongoing basis to comply with Section VIII of this Final Judgment. Defendants shall deliver to plaintiffs an affidavit describing any changes to the efforts and actions outlined in defendants' earlier affidavits filed pursuant to this section within fifteen (15) calendar days after the change is implemented.

C. Defendants shall keep all records of all efforts made to preserve and divest the Divestiture Assets until one year after such divestitures have been completed.

X. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment or whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, authorized representatives of the United States Department of Justice (including consultants and other persons retained by plaintiff United States) shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to defendants, be permitted:

(1) Access during defendants' office hours to inspect and copy, or at plaintiff United States's option, to require defendants to provide hard copy or electronic copies of, all books, ledgers, accounts, records, data and documents in the possession, custody, or control of defendants, relating to any matters contained in this Final Judgment; and

(2) To interview, either informally or on the record, defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, defendants shall submit written reports or response to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in this section shall be divulged by plaintiff United States to any person other than an authorized representative of the executive branch of plaintiff United States or, pursuant to a customary protective order or waiver of confidentiality by defendants, the FCC, except in the course of legal proceedings to which plaintiff United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time information or documents are furnished by defendants to plaintiff United States, defendants represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(l)(G) of the Federal Rules of Civil Procedure, and defendants mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(l)(G) of the Federal Rules of Civil Procedure,'' then plaintiff United States shall give defendants ten (10) calendar days notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

XI. No Reacquisition

Defendants may not reacquire or lease any part of the Divestiture Assets during the term of this Final Judgment.

XII. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIII. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten years from the date of its entry.

XIV. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and plaintiff United States's responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date:
Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16.
United States District Judge

In the United States District Court for the District of Columbia

United States Of America and State Of Vermont, Plaintiffs, v. *Verizon Communications Inc. and Rural Cellular Corporation, Defendants.*
Case No. 1:08–cv–00993(EGS).
Judge Emmet G. Sullivan.
Filed: June 10, 2008.

Competitive Impact Statement

Plaintiff United States of America (''United States''), pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. 1 6(h)–(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

Defendants entered into an Agreement and Plan of Merger dated July 29, 2007, pursuant to which Verizon Communications Inc. (''Verizon'') will acquire Rural Cellular Corporation (''RCC''). Plaintiffs United States and the State of Vermont filed a civil antitrust Complaint on June 10, 2008 seeking to enjoin the proposed acquisition. The Complaint alleges that the likely effect of this acquisition would be to lessen competition substantially for mobile wireless telecommunications services throughout Vermont, one geographic area in New York that is contiguous to Vermont, and in northeast Washington, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. This loss of competition would result in consumers facing higher prices, lower quality service and fewer choices of mobile wireless telecommunications services.

At the same time the Complaint was filed, plaintiffs also filed a Preservation of Assets Stipulation and Order and proposed Final Judgment, which are designed to eliminate the anticompetitive effects of the acquisition. Under the proposed Final Judgment, which is explained more fully below, defendants are required to divest RCC's mobile wireless telecommunications services businesses and related assets throughout Vermont, one geographic area in New York that is contiguous to Vermont, and in northeast Washington (''Divestiture Assets''). Under the terms of the Preservation of Assets Order, defendants will take certain steps to ensure that during the pendency of the ordered divestiture: (a) The Divestiture Assets are preserved and operated as competitively independent, economically viable and ongoing businesses; (b) the Divestiture Assets are operated independently and without influence by defendants; and (c) competition is maintained.

Plaintiffs and defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof. Defendants have also stipulated that they will comply with the terms of the Preservation of Assets Stipulation and Order and the proposed Final Judgment from the date of signing of the Preservation of Assets Stipulation and Order, pending entry of the proposed Final Judgment by the Court and the required divestitures. Should the Court decline to enter the proposed Final Judgment, defendants have also committed to continue to abide by its requirements and those of the Preservation of Assets Stipulation and Order until the expiration of time for appeal.

II. Description of the Events Giving Rise to the Alleged Violation

A. The Defendants and the Proposed Transaction

Verizon, with headquarters in New York, is a corporation organized and existing under the laws of the state of Delaware. Verizon is one of the world's largest providers of communications services. Verizon is the second largest mobile wireless telecommunications services provider in the United States as measured by subscribers, provides mobile wireless telecommunications services in 49 states, and serves in excess of 65 million subscribers. In 2007, Verizon earned mobile wireless telecommunications services revenues of approximately $43 billion.

RCC, with headquarters in Alexandria, Minnesota, is a corporation organized and existing under the laws of the state of Minnesota. RCC is the 10th largest mobile wireless telecommunications services provider in the United States, as measured by subscribers and provides mobile wireless telecommunications services in 15 states. It has approximately 790,000 subscribers. In 2007, RCC earned approximately $635.3 million in revenues.

Pursuant to an Agreement and Plan of Merger dated July 29, 2007, Verizon will acquire RCC for approximately $2.67 billion. If this transaction is consummated, Verizon and RCC combined would have approximately 66 million subscribers in the United States, with $44 billion in mobile wireless telecommunications services revenues. The proposed transaction, as initially agreed to by defendants, would lessen competition substantially for mobile wireless telecommunications services throughout Vermont, one geographic area in New York that is contiguous to Vermont, and in northeast Washington. This acquisition is the subject of the Complaint and proposed Final Judgment filed by plaintiffs.

B. Mobile Wireless Telecommunications Services Industry

Mobile wireless telecommunications services allow customers to make and receive telephone calls and obtain data services using radio transmissions without being confined to a small area during the call or data session, and without the need for unobstructed line-of-sight to the radio tower. Mobility is highly valued by customers, as demonstrated by the more than 255 million people in the United States who own mobile wireless telephones. In 2007, revenues from the sale of mobile wireless telecommunications services in the United States were over $138 billion. To meet this desire for mobility, mobile wireless telecommunications services providers must deploy extensive networks of switches and radio transmitters and receivers and interconnect their networks with the networks of wireline carriers and other mobile wireless telecommunications services providers.

In the early to mid-1980s, the FCC issued two cellular licenses (A-block and B-block) in each Metropolitan Statistical Area (''MSA'') and Rural Service Area (''RSA'') (collectively, ''Cellular Marketing Areas'' or ''CMAs''), with a total of 734 CMAs covering the entire United States. Each license consists of 25 MHz of spectrum in the 800 MHz band. The first mobile wireless voice systems using this cellular spectrum were based on analog technology, now referred to as first-generation or ''1G'' technology.

In 1995, the FCC licensed additional spectrum for the provision of Personal Communications Services (''PCS''), a category of services that includes mobile wireless telecommunications services comparable to those offered by cellular licensees. These licenses are in the 1900 MHz band and are divided into six blocks: A, B, and C, which consist of 30 MHz each; and D, E, and F, which consist of 10 MHz each. Geographically, the A and B-block 30 MHz licenses are issued by Major Trading Areas (''MTAs''). C, D, E, and F-block licenses are issued by Basic Trading Areas (''BTAs''), several of which comprise each MTA. MTAs and BTAs do not generally correspond to MSAs and RSAs.

With the introduction of the PCS licenses, both cellular and PCS licensees began offering digital services, thereby increasing network capacity, shrinking handsets, and extending battery life. In addition, in 1996, one provider, a specialized mobile radio (''SMR'' or ''dispatch'') spectrum licensee, began to use its SMR spectrum to offer mobile wireless telecommunications services comparable to those offered by other mobile wireless telecommunications services providers, in conjunction with its dispatch, or ''push-to-talk,'' service. Although there are a number of providers holding spectrum licenses in each area of the country, not all providers have fully built out their networks throughout each license area. In particular, because of the characteristics of PCS spectrum, providers holding this type of spectrum generally have found it less attractive to build out in rural areas.

Today, more than 95 percent of the total U.S. population lives in counties where three or more mobile wireless telecommunications services operators offer service. Nearly all mobile wireless voice services have migrated to second-generation or ''2G'' digital technologies, GSM (global standard for mobility), and CDMA (code division multiple access). Even more advanced technologies (''2.5G'' and ''3G''), based on the earlier 2G technologies, have been deployed for mobile wireless data services. Additionally, during the past two years, the FCC has auctioned off additional spectrum that can be used to support mobile wireless telecommunications services, including Advanced Wireless Spectrum (1710–1755 MHz and 2110–2155 MHz bands) and 700 MHz band spectrum, although it will be several years before mobile wireless telecommunications services based on this spectrum are widely deployed.

C. The Competitive Effects of the Transaction on Mobile Wireless Telecommunications Services

Mobile wireless telecommunications services include both voice and data services provided over a radio network and allow customers to maintain their telephone calls or data sessions without wires when traveling. There are no cost-effective alternatives to mobile wireless telecommunications services. Because fixed wireless services are not mobile, they are not regarded by consumers of mobile wireless telecommunications services to be a reasonable substitute for those services. It is unlikely that a sufficient number of customers would switch away from mobile wireless telecommunications services to make a small but significant price increase in those services unprofitable.

The United States comprises numerous local geographic markets for mobile wireless telecommunications services.[1] A large majority of customers use mobile wireless telecommunications services in close proximity to their workplaces and homes. Thus, customers purchasing mobile wireless telecommunications services choose among mobile wireless telecommunications services providers that offer services where they live, work, and travel on a regular basis. The geographic areas in which the FCC has licensed mobile wireless telecommunications services providers often represent the core of the business and social sphere within which customers have the same competitive choices for mobile wireless telephone services. The number and identity of mobile wireless telecommunications services providers vanes among geographic areas, as does the quality of services and breadth of geographic coverage offered by providers. Some mobile wireless telecommunications services providers can and do offer different promotions, discounts, calling plans, and equipment subsidies in different geographic areas, varying the price for customers by geographic area.

The relevant geographic markets, under Section 7 of the Clayton Act, 15 U.S.C. 18, where the transaction will substantially lessen competition for mobile wireless telecommunications services are effectively represented by the following FCC spectrum licensing areas: Burlington, Vermont (CMA 248); New York RSA–2 (CMA 560); Vermont RSA–l (CMA 679); Vermont RSA–2 (CMA 680); Washington RSA–2 (CMA 694); and Washington RSA–3 (CMA 695). It is unlikely that a sufficient number of customers would switch to mobile wireless telecommunications services providers who do not offer services in these geographic areas to make a small but significant price increase in the relevant geographic markets unprofitable.

These geographic areas of concern for mobile wireless telecommunications services were identified via a fact-specific, market-by-market analysis that included consideration of, but was not limited to, the following factors: the number of mobile wireless telecommunications services providers and their competitive strengths and weaknesses; Verizon's and RCC's market shares, along with those of the other providers; whether additional spectrum is, or is likely soon to be, available; whether any providers are limited by insufficient spectrum or other factors in their ability to add new customers; the concentration of the market, and the breadth and depth of coverage by different providers in each area and in the surrounding area; and the likelihood that any provider would expand its existing coverage or that new providers would enter.

In each of the cellular license areas described above, Verizon and RCC are the two largest carriers (based on subscribers), with a combined share in each area ranging from over 60% to nearly 94%, and are each other's closest competitor for a significant set of customers. In all but a portion of one of these cellular license areas, Verizon and RCC hold all of the cellular spectrum licenses. In a portion of the Vermont RSA 2 license area (consisting of Bennington and Windham counties, and the portion of Windsor County south of U.S. Route 4), Verizon does not own cellular spectrum, but it is a strong competitor because, unlike many other providers with PCS spectrum in rural areas, it has constructed a PCS network that covers a significant portion of the population, supplements that network with roaming on another carrier's cellular network and plans to substantially expand its own PCS network in the future. Thus, even in that area, Verizon and RCC are the leading two competitors in terms of share. Taking into account the factors that potentially impact competition including coverage area, brand recognition, service quality and reputation, handset selection, and service features, Verizon and RCC are stronger competitors, and thus closer substitutes for each other for a significant set of customers, than the other cellular provider, and the other PCS providers, that serve this area.

The relevant geographic areas for mobile wireless services are also highly concentrated. As measured by the Herfindahl-Hirschman Index (''HHI''), which is commonly employed in merger analysis and is defined and explained in Appendix A to this Complaint, concentration in these areas ranges from over 2800 to more than 5100, which is well above the 1800 threshold at which plaintiffs consider a market to be highly concentrated. After Verizon's proposed acquisition of RCC is consummated, the HHIs in the relevant geographic areas will range from over 4900 to over 8700, with increases in the HHI as a result of the merger ranging from over 1200 to over 4200, significantly beyond the thresholds at which plaintiffs consider a transaction likely to cause competitive harm.

Competition between Verizon and RCC in the relevant geographic areas has resulted in lower prices and higher quality in mobile wireless telecommunications services than would otherwise have existed in these geographic areas. If Verizon's proposed acquisition of RCC is consummated, the competition between Verizon and RCC in mobile wireless telecommunications services will be eliminated in these areas and the relevant geographic areas for mobile wireless telecommunications services will become substantially more concentrated. As a result, the loss of competition between Verizon and RCC increases the merged firm's incentive and ability in the relevant geographic markets to increase prices, diminish the quality or quantity of services provided, and refrain from or delay making investments in network improvements.

Entry by a new mobile wireless services provider in the relevant geographic areas would be difficult, time-consuming, and expensive, requiring spectrum licenses and the build out of a network. Therefore, any entry in response to a small but significant price increase for mobile wireless telecommunications services by the merged firm in these relevant geographic areas would not be timely, likely, or sufficient to thwart the competitive harm resulting from Verizon's proposed acquisition of RCC, if it were to be consummated.

For these reasons, plaintiffs concluded that Verizon's proposed acquisition of RCC will likely substantially lessen competition, in violation of Section 7 of the Clayton Act, in the provision of mobile wireless telecommunications services in the relevant geographic areas alleged in the Complaint.

III. Explanation of the Proposed Final Judgment

The divestiture requirements of the proposed Final Judgment will eliminate the anticompetitive effects of the acquisition in mobile wireless telecommunications services in the geographic areas of concern. The proposed Final Judgment requires defendants, within one hundred twenty (120) days after the consummation of the Transaction, or five (5) days after notice of the entry of the Final Judgment by the Court, whichever is later, to divest the Divestiture Assets. The Divestiture Assets are essentially RCC's entire mobile wireless telecommunications services businesses in the geographic areas described herein where Verizon and RCC are each other's closest competitors for mobile wireless telecommunications services. These assets must be divested in such a way as to satisfy plaintiff United States, (and with respect to the Divestiture Assets located in Vermont

[1] The existence of local markets does not, of course, preclude the possibility of competitive effects in a broader geographic area, such as a regional or national area.

upon consultation with plaintiff Vermont), in its sole discretion that the assets will be operated by the purchaser as a viable, ongoing business that can compete effectively in each relevant area. Defendants must take all reasonable steps necessary to accomplish the divestitures quickly and shall cooperate with prospective purchasers.

The proposed Final Judgment requires that a single purchaser acquire the Divestiture Assets in New York and Vermont, and a single purchaser acquire the Divestiture Assets in Washington. This will allow the purchaser of these assets to supply service to customers that require mobile wireless telecommunications services throughout each of these areas in the same way that RCC is currently able to provide that service. This provision resolves concerns about the loss of competition for customers that demand coverage over a combination of FCC licensing areas, in addition to the concerns due to eliminating competition within each licensing area.

Under limited circumstances, defendants are permitted to retain specified portions of RCC's mobile wireless assets in the relevant geographic areas. First, plaintiffs are not requiring the divestiture of the PCS spectrum held by RCC in the RSAs being divested. In requiring the divestitures, plaintiffs seek to make certain that the potential buyer acquires all the assets it may need to be a viable competitor and replace the competition lost by the merger. The 25 MHz of cellular spectrum that must be divested is typically sufficient to support the operation and expansion of the mobile wireless telecommunications services businesses being divested, enabling the buyer to be a viable competitor to the merged entity. Similarly, defendants are not required to divest CDMA equipment on the Mt. Stratton, Vermont tower or the CDMA, TDMA, and analog equipment on the Woodstock, Vermont tower, although they will be required to divest the GSM equipment located on these towers. The CDMA, TDMA and analog equipment located on these towers is not part of the GSM network being divested and therefore is not essential to the operations of the divested business. The Acquirer will receive the GSM network assets it will need to operate effectively in this area. Third, defendant Verizon may retain defendant RCC's Colchester, Vermont switches (an Ericsson AXE 810 and a Lucent SE). Verizon needs the Ericsson switch to provide service to RCC's GSM customers Verizon is acquiring in Maine and New Hampshire, where Verizon currently has only a CDMA network. It also needs the Lucent switch to support CDMA, TDMA, and analog services used predominantly by roaming customers in Massachusetts, New Hampshire, New York, and Vermont.

A potential acquirer of the Divestiture Assets, which include RCC's GSM network, will either already have, or will be able to quickly obtain, GSM switching capability and will not need TDMA or analog switching to support the divested business.

Additionally, in two instances, defendants may seek approval to retain certain spectrum in Vermont. First, in the Burlington MSA, the merged firm wants to retain RCC's PCS spectrum to insure that it has sufficient spectrum to support its wireless telecommunications services. Depending on the identity of the Acquirer, it may not need this additional PCS spectrum to be an effective competitor. Once an Acquirer is presented for approval, plaintiff United States, in its sole discretion upon consultation with Vermont, will determine whether the proposed Acquirer needs the PCS spectrum to insure it can operate a competitive business with Divestiture Assets its receives and whether allowing defendants to keep the cellular spectrum is consistent with the purposes of the Final Judgment. Second, for the portion of Vermont RSA 2 where Verizon does not own the cellular license, defendants are concerned that they will be unable to promptly roll out wireless broadband services to the citizens of Vermont if they cannot retain any of RCC's cellular spectrum in this area. Once an Acquirer is identified, plaintiff United States, in its sole discretion upon consultation with Vermont, will determine whether Verizon should be allowed substitute 10 MHz of RCC's cellular spectrum for the 10 MHz of PCS spectrum it would otherwise retain.

A. Timing of Divestitures

In antitrust cases involving mergers or joint ventures in which the United States seeks a divestiture remedy, it requires completion of the divestitures within the shortest time period reasonable under the circumstances. Section IV.A.g of the proposed Final Judgment in this case requires divestiture of the Divestiture Assets, within one hundred twenty (120) days after the consummation of the Transaction, or five (5) days after notice of the entry of the Final Judgment by the Court, whichever is later. Plaintiff United States in its sole discretion, and with respect to the Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, may extend the date for divestiture of the Divestiture Assets by up to sixty (60) days. Because the FCC's approval is required for the transfer of the wireless licenses to a purchaser, Section IV.A provides that if applications for transfer of a wireless license have been filed with the FCC, but the FCC has not acted dispositively before the end of the required divestiture period, the period for divestiture of those assets shall be extended until five (5) days after the FCC has acted. This extension is to be applied only to the individual Divestiture Assets affected by the delay in approval of the license transfer and does not entitle defendants to delay the divestiture of any other Divestiture Assets for which license transfer approval is not required or has been granted.

The divestiture timing provisions of the proposed Final Judgment will ensure that the divestitures are carried out in a timely manner, and at the same time will permit defendants an adequate opportunity to accomplish the divestitures through a fair and orderly process. Even if all Divestiture Assets have not been divested upon consummation of the transaction, there should be no adverse impact on competition given the limited duration of the period of common ownership and the detailed requirements of the Preservation of Assets Stipulation and Order.

B. Use of a Management Trustee

The Preservation of Assets Stipulation and Order, filed simultaneously with this Competitive Impact Statement, ensures that, prior to divestiture, the Divestiture Assets remain an ongoing business concern. The Preservation of Assets Stipulation and Order is designed to ensure that the Divestiture Assets will be preserved and remain independent of defendants, so that competition is maintained during the pendency of the ordered divestiture.

The Preservation of Assets Stipulation and Order provides for the appointment of a management trustee selected by plaintiff United States, and with respect to Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, to oversee the Divestiture Assets. The appointment of a management trustee in this situation is required because the Divestiture Assets are not independent facilities that can be held separate and operated as stand-alone units by the merged firm. Rather, the Divestiture Assets are an integral part of a larger network and, to maintain their competitive viability and economic value, they should remain part of that network during the divestiture period. A management trustee will oversee the continuing relationship between defendants and these assets, to ensure that these assets are preserved and supported by defendants during this period, yet run independently. The management trustee will have the power to operate the Divestiture Assets in the ordinary course of business, so that they will remain independent and uninfluenced by defendants, and so that the Divestiture Assets are preserved and operated as an ongoing and economically viable competitor to defendants and to other mobile wireless telecommunications services providers. The management trustee will preserve the confidentiality of competitively sensitive marketing, pricing, and sales information; ensure defendants' compliance with the Preservation of Assets Stipulation and Order and the proposed Final Judgment; and maximize the value of the Divestiture Assets so as to permit expeditious divestiture in a manner consistent with the proposed Final Judgment.

The Preservation of Assets Stipulation and Order provides that defendants will pay all costs and expenses of the management trustee, including the cost of consultants, accountants, attorneys, and other representatives and assistants hired by the management trustee as are reasonably necessary to carry out his or her duties and responsibilities. After his or her appointment becomes effective, the management trustee will file monthly reports with plaintiffs setting forth efforts taken to accomplish the goals of the Preservation of Assets Stipulation and Order and the proposed Final Judgment and the extent to which defendants are fulfilling their responsibilities. Finally, the management trustee may become the divestiture trustee, pursuant to the provisions of Section V of the proposed Final Judgment.

C. Use of a Divestiture Trustee

In the event that defendants do not accomplish the divestiture within the periods

prescribed in the proposed Final Judgment, the Final Judgment provides that the Court will appoint a trustee selected by plaintiff United States, and with respect to Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, to effect the divestitures. As part of this divestiture, defendants must relinquish any direct or indirect financial ownership interests and any direct or indirect role in management or participation in control. Pursuant to Section V of the proposed Final Judgment, the divestiture trustee will own and control the Divestiture Assets until they are sold to a final purchaser, subject to safeguards to prevent defendants from influencing their operation.

Section V details the requirements for the establishment of the divestiture trust, the selection and compensation of the divestiture trustee, the responsibilities of the divestiture trustee in connection with the divestiture and operation of the Divestiture Assets, and the termination of the divestiture trust. The divestiture trustee will have the obligation and the sole responsibility, under Section V.D, for the divestiture of any transferred Divestiture Assets. The divestiture trustee has the authority to accomplish divestitures at the earliest possible time and ''at such price and on such terms as are then obtainable upon reasonable effort by the Divestiture Trustee.'' In addition, to ensure that the divestiture trustee can promptly locate and divest to an acceptable purchaser, United States, in its sole discretion, and with respect to Divestiture Assets located in Vermont upon consultation with plaintiff Vermont, may require defendants to include additional assets, or allow defendants to substitute substantially similar assets, which substantially relate to the Divestiture Assets to be divested by the divestiture trustee.

The divestiture trustee will not only have responsibility for sale of the Divestiture Assets, but will also be the authorized holder of the wireless licenses, with full responsibility for the operations, marketing, and sales of the wireless businesses to be divested, and will not be subject to any control or direction by defendants. Defendants will no longer have any role in the ownership, operation, or management of the Divestiture Assets other than the right to receive the proceeds of the sale. Defendants will also retain certain obligations to support to the Divestiture Assets and cooperate with the divestiture trustee in order to complete the divestiture.

The proposed Final Judgment provides that defendants will pay all costs and expenses of the divestiture trustee. The divestiture trustee's commission will be structured, under Section V.G of the proposed Final Judgment, so as to provide an incentive for the divestiture trustee based on the price obtained and the speed with which the divestitures are accomplished. After his or her appointment becomes effective, the divestiture trustee will file monthly reports with the Court and plaintiffs setting forth his or her efforts to accomplish the divestitures. Section V.J requires the divestiture trustee to divest the Divestiture Assets to an acceptable purchaser or purchasers no later than six (6) months after the assets are transferred to the divestiture trustee. At the end of six (6) months, if all divestitures have not been accomplished, the trustee and plaintiffs will make recommendations to the Court, which shall enter such orders as appropriate in order to carry out the purpose of the Final Judgment, including extending the trust or term of the trustee's appointment.

The divestiture provisions of the proposed Final Judgment will eliminate the anticompetitive effects of the transaction in the provision of mobile wireless telecommunications services. The divestitures of the Divestiture Assets will preserve competition in mobile wireless telecommunications services by maintaining an independent and economically viable competitor in the relevant geographic areas.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register** or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, which ever is later. All comments received during this period will be considered by the Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of plaintiff United States will be filed with the Court and published in the **Federal Register**.

Written comments should be submitted to: Nancy M. Goodman, Chief, Telecommunications and Media Enforcement Section, Antitrust Division, U.S. Department of Justice, 1401 H Street, NW., Suite 8000, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

Plaintiffs considered, as an alternative to the proposed Final Judgment, a full trial on the merits against defendants. Plaintiffs could have continued the litigation and sought preliminary and permanent injunctions against Verizon's acquisition of RCC. Plaintiffs are satisfied, however, that the divestiture of assets and other relief described in the proposed Final Judgment will preserve competition for the provision of mobile wireless telecommunications services in the relevant areas identified in the Complaint.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

A. The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

B. The impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reach of the public interest.'' *United States* v. *Microsoft Corp,* 56 F.3d 1448, 1461 (DC. Cir. 1995); *see generally United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1, 11 (D.D.C. 2007) (assessing the public interest standard under the Tunney Act).[2]

[2] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for a court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. Compare 15 U.S.C. § 16(e) (2004), with 15 U.S.C. § 16(e)(1) (2006); see also SBC Commc'ns, 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (citing *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001). Courts have held that:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[3] In determining whether a proposed settlement is in the public interest, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' SBC *Commc'ns,* 489 F. Supp. 2d at 17; *see also Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have great flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.' '' *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975)), *affdsub nom. Maryland* v. *United States,* 460 U.S. 1001 (1983); see also *United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459. Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Id.* at 1459–60. As this Court recently confirmed in *SBC Communications,* courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' *SBC Commc'ns,* 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2). The language wrote into the statute what the Congress that enacted the Tunney Act in 1974 intended, as Senator Tunney then explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns*, 489 F. Supp. 2d at 11.[4]

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by plaintiff United States in formulating the proposed Final Judgment.

Dated: June 10, 2008.

Respectfully submitted,

Hillary B. Burchuk (DC Bar No. 366755),

Lawrence M. Frankel (DC Bar No. 441532),

Jared A. Hughes,

Deborah Roy (DC Bar No. 452573),

Attorneys, Telecommunications & Media Enforcement Section, Antitrust Division, U.S. Department of Justice, City Center Building, 1401 H Street, NW., Suite 8000, Washington, DC 20530, (202) 514–5621, Facsimile: (202) 514–6381.

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DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Open Mobile Alliance

Notice is hereby given that, on April 25, 2008, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Open Mobile Alliance (''OMA'') filed written

[3] *Cf BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest' '').

[4] *See United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); *United States* v. *Mid-Am. Dairymen, Inc.,* 1977–1 Trade Cas. (CCH) 11 61,508, at 71,980 (W.D. Mo. 1977) (''Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.''); S. Rep. No. 93–298, 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Adaptive Mobile Security Ltd., Dublin, IRELAND; Adobe Systems Incorporated, San Francisco, CA; AltGen Co., Ltd., Mapo-Gu, Seoul, REPUBLIC OF KOREA; Amobee, Herzlia, ISRAEL; Axel Technologies, Turku, FINLAND; Best of the Web, Uniondale, NY; Cable Television Laboratories, Inc., Louisville, CO; Cambridge Silicon Radio plc, Cambridge, UNITED KINGDOM; castLabs GmbH, Berlin, GERMANY; Cell Guide, Rehorot, ISRAEL; Cisco Systems, Milpitas, CA; Cloudmark, Inc., San Francisco, CA; Communigate Systems, Mill Valley, CA; Connectivity Communications Limited, London, UNITED KINGDOM; decontis GmbH, Loebau, GERMANY; Digicert SSL Certificate Authority, Lindon, UT; DKI Technology Inc., Young deungpo-gu, Seoul, REPUBLIC OF KOREA; Dynamic Motion Technologies, Ipoh, Perak, MALAYSIA; Eluon Corporation, Seocho-Gu, Seoul, REPUBLIC OF KOREA; EnSoft Co., Ltd., Guro-gu, Seoul, REPUBLIC OF KOREA; Entosys Co., Ltd., Mapo-Gu, Seoul, REPUBLIC OF KOREA; Gemalto N.V., Amsterdam, THE NETHERLANDS; GoldSpot Media Inc., Sunnyvale, CA; Hand Cell Phone, Chattanooga, TN; Handmark, Inc.; Kansas City, MO; Hellosoft, Inc., Andhoa Pradesh, INDIA; INKA Entworks, Inc., Kangnam-Gu, Seoul, REPUBLIC OF KOREA; Intertrust Technologies Corporation, Sunnyvale, CA; INTICUBE Corp., Jung-gu, Seoul, REPUBLIC OF KOREA; Intrinsyc Software International, Inc., Bellevue, WA; I–ON Communications Co., Ltd., Gangnam-gu, Seoul, REPUBLIC OF KOREA; Kimia Solutions S.L., Madrid, SPAIN; Motive Inc., Austin, TX; Mtag, Paris, FRANCE; Nable Communications, Inc., Kangnam-Gu, Seoul, REPUBLIC OF KOREA; NeoMedia Technologies, Inc., Atlanta, GA; Nokia Siemens Networks, Munich, GERMANY; NOW Wireless Ltd., Croydon, UNITED KINGDOM; NTT Advanced Technology Corporation, Tokyo, JAPAN; NTT Multimedia Communications Laboratories, Inc., San Mateo, CA; Palm, Inc., Sunnyvale, CA; Payzy Corp., Koongtoey, Bangkok, THAILAND; Point-I Co., Ltd., Gangnam-Gu, Seoul, REPUBLIC OF KOREA; Porss Technology Co., Ltd., Xicheng District, Beijing, PEOPLE'S REPUBLIC OF CHINA; RealNetworks, Inc., Seattle, WA; RRD Reti Radiotelevisive Digitali, S.p.A, Milan, ITALY; RSystems Inc., El Dorado Hills, CA; Rx Networks, Vancouver, BC, CANADA; Scanbuy, Inc., New York, NY; Silicon & Software Systems Limited, Leopardstown, Dublin, IRELAND; Sintesio Foundation, Bled, SLOVENIA; Softbank Mobile Corp., Minato-ku, Tokyo, JAPAN; Solaiemes, Madrid, SPAIN; Sunplus mMobile, Hsinchu Science Park, TAIWAN; Syniverse Technologies, Inc., Tampa, FL; Telcordia, Piscataway, NJ; Telcoware Co., Ltd., Seocho-Gu, Seoul, REPUBLIC OF KOREA; Telogic Sdn. Bhd., Petaling Jaya, Selangor, MALAYSIA; Thin Multimedia, Inc., Seocho-Ku, Seoul, REPUBLIC OF KOREA; THOMSON, Cesson-Sevigne, FRANCE; TruePosition, Inc., Berwyn, PA; Ulticom Incorporated, Mt. Laurel, NJ; V4X SAS, Bordeaux Pessac, FRANCE; Vidiator, Bellevue, WA; Vishwak Solutions Pvt. Ltd., Chennai, INDIA; Webmessenger Inc., Tujunga, CA; weComm Limited, London, UNITED KINGDOM; Welgate Corp., Seocho Dong, Seoul, REPUBLIC OF KOREA; WRG, Inc., Seongnam-Si, Gyeonggi-Do, REPUBLIC OF KOREA; and Yahoo, Inc., Sunnyvale, CA, have been added as parties to this venture.

Also, Ad Vitam, Olivet, FRANCE; Adamind, Ra'anana, ISRAEL; Advanced Strategies Corp., Garden City, NY; ATIO Corporation, Coombe Place, Rivonia, REPUBLIC OF SOUTH AFRICA; BenQ Mobile, Munich, GERMANY; Bitfone Corporation, Laguna Niguel, CA; Bytemobile, Inc., Mountain View, CA; CA Inc., Islandia, NY; Ceno Technologies, Ltd., Shanghai, PEOPLE'S REPUBLIC OF CHINA; Consistec Engineering & Consulting, Saarbrucken, GERMANY; Contec Innovations Inc., Port Coquitlam, BC, CANADA; Dai Nippon Printing Co. Ltd., Toshima-ku, Tokyo, JAPAN; DxO Labs, Boulogne, FRANCE; Edge Technologies, Inc., Fairfax, VA; Elcoteq SE, Salo, FINLAND; Emirates Telecommunications Corporation, Abu Dhabi, UNITED ARAB EMIRATES; Estacado Systems, LLC, Dallas, TX; Faith, Inc., Kyoto, JAPAN; Fastmobile Inc., Rolling Meadows, IL; Finnet-liitto ry, Helsinki, FINLAND; Firsthop, Helsinki, FINLAND; Fraunhofer Institut, Ilmenau, GERMANY; Freescale Semiconductor Inc., Austin, TX; gate5 AG, Berlin, GERMANY; Global Locate, San Jose, CA; GloNav, Inc., Newport Beach, CA; Huone Inc., Daegu, REPUBLIC OF KOREA; IC3S Information, Computer Solartechnik AG, Quickborn, GERMANY; I'M Technologies Ltd., The Signature, SINGAPORE; Incony AG, Paderborn, GERMANY; INNVO Systems, SINGAPORE; Insignia Solutions, Fremont, CA; Institute for Information Industry, Taipei, TAIWAN; Integration Services & Technologies Pty Ltd., Downer, ACT, AUSTRALIA; Inventec Appliances (Jiangning) Corporation, Nanjing, PEOPLE'S REPUBLIC OF CHINA; Leadtone Wireless Ltd., Chaoyang District, Beijing, PEOPLE'S REPUBLIC OF CHINA; Linkuall-Alcomia, Bordeaux, FRANCE; McAfee, Inc., Santa Clara, CA; Microelectronica Espanola, Madrid, SPAIN; Micromethod Technologies, Inc., San Jose, CA; Miyowa, Marseille, FRANCE; Mobile Cohesion, Belfast, UNITED KINGDOM; Mobilitec, Inc., San Mateo, CA; MStar Semiconductor, Inc., Hsinchu Hsien, TAIWAN; NDS Israel, Jerusalem, ISRAEL; Netxcalibur SRL, Florence, ITALY; Norbelle, LLC, Rancho Palos Verdes, CA; NTT Advanced Technology Corp. (OLD), Musashino-shi, Tokyo, JAPAN; NTT Software Corporation, Mitaka-shi, Tokyo, JAPAN; 02, Slough, UNITED KINGDOM; ObexCode AS, Oslo, NORWAY; OSS Nokalva Inc., Somerset, NJ; Prodyne Technologies Inc., St. Catharines, Ontario, CANADA; Quanta Computer Inc., Tao Yuan Shien, TAIWAN; Renesas Technology Corp., Chiyoda-ku, Tokyo, JAPAN; Sasken Communication Technologies Limited, Bangalore, INDIA; Savaje Technologies, Chelmsford, MA; Smart Internet Technology, Eveleigh, NSW, AUSTRALIA; Smartfone Limited, Hong Kong, HONG KONG–CHINA; Sonus Networks, Inc., Chelmsford, MA; Square Enix, Inc., El Segundo, CA; TechnoCom Corporation, Carlsbad, CA; Teleca Sweden AB, Lund, SWEDEN; Telefonica Moviles, Madrid, SPAIN; TeleworX Group, Inc., McLean, VA; Telus Mobility, Scarborough, Ontario, CANADA; Texas Instruments, Incorporated, Dallas, TX; UK Department of Trade and Industry, London, UNITED KINGDOM; Verisign, Inc., Mountain View, CA; VIDA Software, S.L., Barcelona, SPAIN; Visa International Services Association, Foster City, CA; Vodafone IT Hizmetleri A.S., Istanbul, TURKEY; WiderThan, Seoul, REPUBLIC OF KOREA; and Wireless Technologies Oy, Espoo, FINLAND, have withdrawn as parties to this venture.

In addition, the following members have changed their names: LogicaCMG to Acision; Appium AB to AePona Ltd.; Alcatel to Alcatel-Lucent; Flextronics Software Systems to Aricent; Cingular Wireless to AT&T; IntroMobile Co., Ltd. to Insprit; Nortel Networks to Nortel; Telenor Mobil to Telenor ASA.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and OMA intends to file additional written notifications disclosing all changes in membership.

On March 18, 1998, OMA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on December 31, 1998 (63 FR 72333).

The last notification was filed with the Department on January 18, 2007. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on February 26, 2007 (72 FR 8401).

J. Robert Kramer, II,

Director of Operations, Antitrust Division.

[FR Doc. E8–14596 Filed 6–26–08; 8:45 am]

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DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—International SAE Consortium Ltd. (Formerly Known as SAE Consortium Ltd.)

Notice is hereby given that, on May 21, 2008, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), International SAE Consortium Ltd. (''ISAEC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Daiichi Sankyo, Inc., Edison, NJ; Takeda Global Research and Development Center, Inc., Deerfield, IL; and The Wellcome Trust, London, UNITED KINGDOM have been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and ISAEC intends to file additional written notification disclosing all changes in membership.

On September 27, 2007, ISAEC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 7, 2007 (72 FR 62867).

The last notification was filed with the Department of Justice on January 25, 2008. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on March 4, 2008 (73 FR 11680).

J. Robert Kramer, II,

Director of Operations, Antitrust Division.

[FR Doc. E8–14597 Filed 6–26–08; 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—Testing of Methods for Measuring Hydrocarbon Dew Points in Natural Gas Streams

Notice is hereby given that, on May 13, 2008, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. (''the Act''), SwRI: Testing of Methods for Measuring Hydrocarbon Dew Points in Natural Gas Streams has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its nature and objective. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the period of performance has been extended to July 31, 2008.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and SwRI intends to file additional written notifications disclosing all changes in membership.

On March 20, 2007, SwRI: Testing of Methods for Measuring Hydrocarbon Dew Points in Natural Gas Streams filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on April 16, 2007 (72 FR 19023).

The last notification was filed with the Department on October 30, 2007. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on December 20, 2007 (72 FR 72389).

J. Robert Kramer, II,

Director of Operations, Antitrust Division.

[FR Doc. E8–14598 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a registration under 21 U.S.C. 952(a)(2) authorizing the importation of such substances, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on May 13, 2008, Aptuit (Allendale) Inc., 75 Commerce Drive, Allendale, New Jersey 07401, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of Noroxymorphone (9668), a basic class of controlled substance listed in schedule II.

The company plans to import the basic class of controlled substance for clinical trials and research.

Any manufacturer who presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than July 28, 2008.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance listed in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements

for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: June 19, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E8–14586 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a registration under 21 U.S.C. 952(a)(2) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Title 21 Code of Federal Regulations (CFR), 1301.34(a), this is notice that on May 8, 2008, Aptuit, 10245 Hickman Mills Drive, Kansas City, Missouri 64137, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Marihuana (7360), a basic class of controlled substance listed in schedule I.

The company plans to import a finished pharmaceutical product containing cannabis extracts in dosage form for packaging for a clinical trial study.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, VA 22152; and must be filed no later than July 28, 2008.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: June 19, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E8–14590 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated March 19, 2008 and published in the **Federal Register** on March 28, 2008, (73 FR 16718), Penick Corporation, 33 Industrial Park Road, Pennsville, New Jersey 08070, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Coca Leaves (9040)	II
Opium, raw (9600)	II
Poppy Straw (9650)	II
Concentrate of Poppy Straw (9670).	II

The company plans to import the listed controlled substances to manufacture bulk controlled substance intermediates for sale to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Penick Corporation to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Penick Corporation to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: June 19, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E8–14584 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated March 27, 2008 and published in the **Federal Register** on April 2, 2008, (73 FR 18000), Stepan Company, Natural Products Department, 100 W. Hunter Avenue, Maywood, New Jersey 07607, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Coca Leaves (9040), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance for the manufacture of a bulk controlled substance for distribution to its customer.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and § 952(a) and determined that the registration of Stepan Company to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Stepan Company to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company

is granted registration as an importer of the basic class of controlled substance listed.

Dated: June 20, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E8–14651 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 22, 2008, Norac Inc., 405 S. Motor Avenue, P.O. Box 577, Azusa, California 91702–3232, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Gamma Hydroxybutyric Acid (2010), a basic class of controlled substance listed in schedule I.

The company plans to manufacture the listed controlled substance in bulk for sale to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such a substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than August 26, 2008.

Dated: June 19, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E8–14585 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 7, 2008, Archimica, Inc., 2460 W. Bennett Street, Springfield, Missouri 65807–1229, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Methylphenidate (1724)	II
Phenylacetone (8501)	II
Methadone Intermediate (9254)	II

The company plans to manufacture the listed controlled substances in bulk for research purposes, and sale to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than August 26, 2008.

Dated: June 20, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E8–14588 Filed 6–26–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,632]

Lear Idea Center, Seating Systems Division, Madison Heights, MI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on July 5, 2007, applicable to workers of Lear Idea Center, Seating Systems Division, Madison, Michigan. The notice was published in the **Federal Register** on July 19, 2007 (72 FR 39643).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers produced auto seating trim.

The certification incorrectly stated that the certification was for workers of Lear Idea Center, Seating Systems Division in Madison, Michigan. The city named in the certification document should have been Madison Heights, not Madison. Therefore, the Department is amending this certification to correctly identify the city in which the worker group is located.

The amended notice applicable to TA–W–61,632 is hereby issued as follows:

All workers of Lear Idea Center, Seating Systems Division, Madison Heights, Michigan, who became totally separated from employment on May 29, 2006 through July 5, 2009, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC, this 19th day of June 2008.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–14604 Filed 6–26–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W–62,626]

Visteon Systems LLC, Bedford Plant, a Subsidiary of Visteon Corporation, Including On-Site Leased Workers from Securitas, Including Leased Workers From Bedford Logistics, Inc., Bedford, IN; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on February 27, 2008, applicable to workers of Visteon Systems LLC, Bedford Plant, a subsidiary of Visteon Corporation, including on-site leased workers from Securitas, Bedford, Indiana. The notice was published in the **Federal Register** on March 11, 2008 (73 FR 13017).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of automotive components (i.e. fuel delivery modules, wiper reservoirs and canister vent valves).

New information shows that leased workers of Bedford Logistics, Inc., Bedford, Indiana are in support of and sufficiently under the control of the Bedford, Indiana facility of Visteon Systems LLC, Bedford Plant.

Based on these findings, the Department is amending this certification to include leased workers from Bedford Logistics working in support of the Bedford, Indiana location of the subject firm.

The intent of the Department's certification is to include all workers of Visteon Systems LLC, Bedford Plant, a subsidiary of Visteon Corporation who were adversely affected by increased imports of Automotive components (i.e. fuel delivery modules, wiper reservoirs, and canister vent valves).

The amended notice applicable to TA–W–62,626 is hereby issued as follows:

All workers of Visteon Systems LLC, Bedford Plant, a subsidiary of Visteon Corporation, including on-site leased workers from Securitas and including leased workers from Bedford Logistics in support of Visteon Systems LLC, Bedford Plant, a subsidiary of Visteon Corporation, Bedford, Indiana, who became totally or partially separated from employment on or after January 21, 2008, through February 27, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC this 20th day of June 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–14605 Filed 6–26–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *June 9 through June 13, 2008.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. the sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. there has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. the country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. there has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) either—

(A) the workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (*i.e.* , conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–63,187; Baldwin Hardware Corporation, Reading, PA: October 12, 2007.

TA–W–63,231; Steelcase, Inc., Wood Plant, Caledonia, MI: April 18, 2007.

TA–W–63,251; Culp Woven Fabrics, A Division of Culp, Inc., Anderson, SC: April 23, 2007.

TA–W–63,275; Plastic Trim International, Inc., Beavercreek Division, Dayton, OH: April 28, 2007.

TA–W–63,302; BCS Cuyahoga, LLC, Subsidiary of BCS Industries, LLC, Solon, OH: May 2, 2007.

TA–W–63,357; Hanes Industries, A Subsidiary of Hanes Companies, Conover, NC: May 7, 2007.

TA–W–63,391; Pope and Talbot, Inc., Pulp Division, Halsey, OR: May 13, 2007.

TA–W–63,420D; Bernhardt Furniture Company, Plant 10, Cherryville, NC: May 20, 2007.

TA–W–62,825; Smart Parts, Inc., Loyalhanna, PA: February 9, 2007.

TA–W–62,825A; Smart Parts, Inc., Greensburg,PA: February 9, 2007.

TA–W–63,053; Mohawk ESV, Inc., Hiawassee, GA: March 12, 2007.

TA–W–63,181; The Hall China Company, East Liverpool, OH: June 9, 2007.

TA–W–63,211; Glen Gery Corporation, Somerville, NJ: April 11, 2007.

TA–W–63,228; Galey and Lord Industries, LLC, dba Swift Galey, Columbus, GA: April 21, 2007.

TA–W–63,228A; Galey and Lord Industries, LLC, dba Swift Galey, Atlanta, GA: April 21, 2007.

TA–W–63,228B; Galey and Lord Industries, LLC, dba Swift Galey, Employees of Galey and Lord, Inc. LLC, Greensboro, NC: April 21, 2007.

TA–W–63,228C; Galey and Lord Industries, LLC, dba Swift Galey, Employees of Galey and Lord, Inc. LLC, Los Angeles, CA: April 21, 2007.

TA–W–63,228D; Galey and Lord Industries, LLC, dba Swift Galey, Employees of Galey and Lord, Inc. LLC, Yeardley, PA: April 21, 2007.

TA–W–63,228E; Galey and Lord Industries, LLC, dba Swift Galey, Employees of Galey and Lord, Inc. LLC, San Francisco, CA: April 21, 2007.

TA–W–63,228F; Galey and Lord Industries, LLC, dba Swift Galey, Employees of Galey and Lord, Inc. LLC, Dallas, TX: April 21, 2007.

TA–W–63,228G; Galey and Lord Industries, LLC, dba Swift Galey, New York, NY: April 21, 2007.

TA–W–63,232; GAE Warren, LLC, Warren, OH: April 21, 2007.

TA–W–63,319; Hood Industries Inc., Subsidiary of Hood.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–63,138; Prettl Electric Corporation, Greenville, SC: April 3, 2007.

TA–W–63,271; Horton Automatics, Corpus Christi, TX: April 10, 2007.

TA–W–63,331; Burlington Finishing Plant, BWW Division, Burlington, NC: May 5, 2010.

TA–W–63,411; Pass and Seymour, Concord, NC: May 19, 2007.

TA–W–63,413; Spicer Driveshaft, LLC, A Subsidiary of Dana Corp., Marion, IN: May 12, 2007.

TA–W–63,448; Prestolite Wire, LLC, Tifton, GA: May 29, 2007.

TA–W–63,480; Mitsubishi Kagaku Imaging Corporation, Virginia Division, OPC Manufacturing Group, Chesapeake, VA: May 20, 2007.

TA–W–63,284; Kimball International General Office, A Subsidiary of Kimball International, Jasper, IN: April 29, 2007.

TA–W–63,443; DME Company, Lewiston, PA: May 28, 2007.

TA–W–63,465; Sara Campbell LTD, Boston, MA: June 2, 2007.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older.

None.

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

None.

The Department has determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

TA–W–62,892; Barnes Aerospace, Ceramics Division, Windsor, CT.

TA–W–62,892A; Barnes Aerospace, Windsor Division, Windsor, CT.

TA–W–63,231A; Steelcase, Inc., Global Headquarters Division, Grand Rapids, MI.

TA–W–63,231B; Steelcase, Inc., Corporate Development Center, Caledonia, MI.

TA–W–63,231C; Steelcase, Inc., Kentwood West Plant, Caledonia, MI.

TA–W–63,231D; Steelcase, Inc., Kentwood East Plant, Caledonia, MI.

TA–W–63,231E; Steelcase, Inc., Physical Distribution Center, Kentwood, MI.

TA–W–63,231F; Steelcase, Inc., Steelcase University, Kentwood, MI.

TA–W–63,231G; Steelcase, Inc., Brayton International Division, High Point, NC.

TA–W–63,231H; Steelcase, Inc., Athens Division, Athens, AL.

TA–W–63,231I; Steelcase, Inc., Details Division, Athens, AL.

TA–W–63,231J; Steelcase, Inc., Athens Division, Athens, AL.

TA–W–63,231K; Steelcase, Inc., Vecta Division, Grand Prairie, TX.

TA–W–63,231L; Steelcase, Inc., Hedberg Data Systems Division, East Windsor, CT.

TA–W–63,420; Bernhardt Furniture Company, Corporate Office, Lenoir, NC.

TA–W–63,420A; Bernhardt Furniture Company, Bernhardt Central Warehouse, Lenoir, NC.

TA–W–63,420B; Bernhardt Furniture Company, Plant 6/11, Lenoir, NC.

TA–W–63,420C; Bernhardt Furniture Company, Plant 9, Shelby, NC.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–63,404; FMC Corporation, South Charleston, WV.

TA–W–63,418; Gramercy Jewelry Manufacturing Corp., New York, NY.

TA–W–63,480A; Mitsubishi Kagaku Imaging Corporation, Virginia Division, Toner Manufacturing Group, Elkton, MD.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–62,981; Georgia Pacific Wood Products South, LLC, Wood Products Division, Plywood Plant, Springhill, LA.

TA–W–62,981A; Georgia Pacific Wood Products South, LLC, Wood Products Division, Lumber Operations, Springhill, LA.

TA–W–63,069; Milprint, Inc., A Subsidiary of Bemis Company, Lancaster, WI.

TA–W–63,091; FarNorth Window and Doors, Subsidiary of Scherer Brothers Lumber Co., Window & Door Division, Champlin, MN.

TA–W–63,131; Pfizer, Inc., Terre Haute, IN.

TA–W–63,220; Starbrook Industries, Inc., Covington, OH.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–63,209; Novartis Pharmaceuticals Corporation, Customer Call Center, East Hanover, NJ.

TA–W–63,327; Logistics Services, Inc., Fenton, MO.

TA–W–63,356; TRG Customer Solutions, Greensburg, PA.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.

None.

I hereby certify that the aforementioned determinations were issued during the period of *June 9 through June 13, 2008.* Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: June 20, 2008.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–14603 Filed 6–26–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,547]

Lapeer Metal Stamping, Lapeer, MI; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 17, 2008 in response to a petition filed on behalf of workers of Lapeer Metal Stamping, Lapeer, Michigan.

The petitioning group of workers are covered under by the earlier petition, (TA–W–63,469) filed on June 3, 2008 that is the subject of an ongoing investigation for which a determination has not yet been issued. Further investigation in this case would duplicate efforts and serve no purpose; therefore the investigation under this petition has been terminated.

Signed at Washington, DC, this 20th day of June, 2008.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–14607 Filed 6–26–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,557]

Royal Home Fashions, Plant 4, a Subsidiary Of Croscill, Inc., Durham, NC; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 18, 2008 in response to a petition filed by a company official on behalf of the workers of Royal Home Fashions, Plant 4, a subsidiary of Croscill, Inc., Henderson, North Carolina.

The workers are covered by active certification (TA–W–59,843), which expires on August 31, 2008. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 20th day of June 2008.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–14602 Filed 6–26–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,401]

Unifi, Inc., Staunton, VA; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on May 19, 2008 in response to a petition filed by a company official on behalf of workers at Unifi, Inc., Staunton, Virginia.

The company has requested that the petition be withdrawn. The company intends to submit a new petition closer to the date of separation or threat of separation.

Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 19th day of June 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–14606 Filed 6–26–08; 8:45 am]

BILLING CODE 4510–FN–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting

TIME AND DATE: 10 a.m., Thursday, July 24, 2008.

PLACE: The Richard V. Backley Hearing Room, 9th Floor, 601 New Jersey Avenue, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED:

The Commission will consider and act upon the following in open session: *Secretary of Labor* v. *National Cement Company of California,* Docket No. WEST 2004–182–RM. (Issues include whether the Secretary properly interpreted section 3(h)(1) of the Mine Act in concluding that MSHA had jurisdiction over an access road leading to a cement plant.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Jean Ellen (202) 434–9950/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Sandra G. Farrow,

Acting Chief Docket Clerk.

[FR Doc. E8–14591 Filed 6–26–08; 8:45 am]

BILLING CODE 6735–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(A)]. This program 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, the NEA is soliciting comments concerning the proposed information collection to evaluate the ''Operation Homecoming: Literary Programming for Veterans and Their Families'' initiative. A copy of the current information collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below on or before August 27, 2008. The NEA 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 submissions of responses.

ADDRESSES: Michael McLaughlin, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Room 710, Washington, DC 20506–0001, telephone (202) 682–5457 (this is not a toll-free number), fax (202) 682–5613.

Kathleen Edwards,

Director, Administrative Services, National Endowment for the Arts.

[FR Doc. E8–14547 Filed 6–26–08; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No 50–391]

Tennessee Valley Authority; Watts Bar Nuclear Plant, Unit 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering extending the latest construction completion date specified in Construction Permit No. CPPR–92 issued to Tennessee Valley Authority (permittee, TVA) for the Watts Bar Nuclear Plant (WBN), Unit 2. The facility is located at the permittee's site on the west branch of the Tennessee River approximately 50 miles northeast of Chattanooga, Tennessee.

Environmental Assessment

Identification of Proposed Action

The proposed action would extend the latest construction completion date of Construction Permit No. CPPR–92 from December 31, 2010 to March 31, 2013. The proposed action is in response to the permittee's request dated May 8, 2008. This request superseded an earlier letter dated March 6, 2008.

The proposed extension will not allow any work to be performed that is not already allowed by the existing construction permit. The extension will merely grant the permittee more time to complete construction in accordance with the previously approved construction permit.

The Need for the Proposed Action

The proposed action is needed to give the permittee adequate time to complete construction of WBN Unit 2. In a July 14, 2000 letter, TVA confirmed that

WBN Unit 2 met the NRC's definition of a deferred plant, as described in Generic Letter 87–15, ''Policy Statement on Deferred Plants.'' Subsequently, on August 3, 2007, TVA informed the Commission of its intent to complete construction and licensing of WBN Unit 2 by April 1, 2012; this letter was submitted in accordance with the Policy Statement on Deferred Plants. TVA provided information requested by the Policy Statement, and also informed the Commission that it would resume construction activities no sooner than December 3, 2007. These activities are within the scope of the existing construction permit, which expires December 31, 2010.

Environmental Impacts of the Proposed Action

The environmental impacts associated with the construction of the facility have been previously discussed and evaluated in TVA's Final Environmental Statement for construction (FES–CP) of WBN, Units 1 and 2, issued on November 9, 1972. NRC staff evaluated the environmental impacts of construction and operation of this plant, issuing comments on TVA's FES–CP as part of its review. In December 1978, NRC staff issued NUREG–0498, ''Final Environmental Statement Related to Operation of Watts Bar Nuclear Plant Units 1 and 2,'' for the operating-license stage (FES–OL), addressing environmental impacts of construction activities not addressed previously in TVA's FES–CP. The activities included: (1) Construction of the transmission route for the Watts Bar—Volunteer 500 kV line, (2) construction of the settling pond for siltation control for construction runoff at a different location from that originally proposed in the FES–CP, and (3) the relocation of the blowdown diffuser from the originally proposed site indicated in the FES–CP. The staff addressed the terrestrial and aquatic environmental impacts in the FES–OL, as well as historic and archeological impacts, and concluded that the assessment presented in the FES–CP remains valid.

NUREG–0498, Supplement 1 was issued in April 1995. Environmental issues evaluated included changes to regional demography, natural resource use, meteorology, ecology, impacts to humans and the environment, severe accident mitigation design alternatives, and socioeconomic impacts, including environmental justice issues. The staff concluded that there were no significant changes to the environmental impacts discussed in the 1978 FES–OL due to changes in plant design or operation, or changes in the environment. Furthermore, the staff concluded that no additional impacts not previously discussed in the NRC's 1978 FES–OL related to construction of Unit 2 were expected.

On February 15, 2008, TVA submitted ''Watts Bar Nuclear Plant (WBN)—Unit 2—Final Supplemental Environmental Impact Statement [FSEIS] For the Completion and Operation of Unit 2,'' to the NRC. This FSEIS was completed in June 2007, and was submitted in support of TVA's operating license application for WBN Unit 2. It also includes TVA's evaluation of the environmental impacts of construction.

The licensee has no plans to construct additional transmission lines or disturb any land not discussed in previous environmental reviews. Impacts on the Federal threatened and endangered species list issued by the Fish and Wildlife Service were evaluated in previous NRC environmental reviews. No additional impacts are expected.

Completed construction of WBN Unit 2 includes major structures such as the containment, turbine building, control building, and equipment such as the reactor pressure vessel, reactor coolant system piping, and steam generators. Installation of equipment shared with WBN Unit 1, such as diesel generators, was completed prior to issuance of the Unit 1 operating license in 1996. The majority of construction activities will take place within structures already completed. Therefore, most of the construction impacts discussed in the FES have already occurred. As discussed in TVA's FSEIS, additional onsite construction environmental impacts will be small, mitigated by use of good construction practices.

Socioeconomic impacts are similar to those previously evaluated by the NRC. As construction proceeds, workers moving to the area will increase demand for services such as schools and recreational facilities. In its June 2007 FSEIS, in anticipation of a decision to resume construction, TVA stated that it ''...would designate certain counties as impacted by the construction process. This [designation] would make them eligible for a supplemental allocation from TVA's annual tax equivalent payment under Tennessee law. These funds could be used by counties to address impacts on county services.'' These payments mitigate the effects of new workers living in the area.

The requested extension of the construction permit only extends the period of construction as described in the FES, and does not involve any different impacts as described and analyzed in the original and updated environmental impact statements. The cumulative impacts of the extended construction period are small, and mitigated, as discussed above.

Based on the foregoing, the NRC staff has concluded that the proposed action would have no significant environmental impact. Since this action would only extend the period of construction activities described in the FES, it does not involve any different impacts or a significant change to those impacts described and analyzed in the original environmental impact statement. Consequently, an environmental impact statement addressing the proposed action is not required.

Alternatives to the Proposed Action

A possible alternative to the proposed action would be to deny the request, or the no-action alternative. This alternative would result in expiration of the construction permit for Watts Bar, Unit 2. This option would require submittal of another application for construction in order to allow the permittee to complete construction of the facility with no significant environmental benefit. The environmental impacts of the proposed action and alternative action are similar.

Denial of the request could also result in TVA seeking other sources of electrical power. Siting and constructing new power generating facilities would result in their own environmental impacts, and does not provide an obvious environmental benefit versus the proposed construction permit extension, especially given the large degree of construction already completed for WBN Unit 2.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in the FES for Watts Bar, Units 1 and 2.

Agencies and Persons Contacted

In accordance with its stated policy, on May 28, 2008, the staff consulted with officials from the State of Tennessee, including Alan Leiserson, Legal Services Director of the Tennessee Department of Environment and Conservation, regarding the environmental impact of the proposed action. The State officials had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that this action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an

environmental impact statement for this action.

For further details with respect to this action, see the licensee's request for extension dated May 8, 2008. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading room on the internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or send an e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland this 20th day of June 2008.

For the Nuclear Regulatory Commission.

L. Raghavan,

Chief, Watts Bar Special Projects Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E8–14594 Filed 6–26–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Subcommittee Meeting on Power Uprates (Millstone Unit 3); Corrected Notice of Meeting (Corrected To Note Millstone Unit 3 Instead of Hope Creek)

The ACRS Subcommittee on Power Uprates will hold a meeting on July 8, 2008, at 11545 Rockville Pike, Rockville, Maryland, Room T–2B3.

The meeting will be open to public attendance, with the exception of portions that may be closed to discuss proprietary information pursuant to 5 U.S.C. 552b(c)(4) for presentations covering information that is proprietary to Dominion Nuclear Connecticut, Inc. (DNC) or its contractor Westinghouse Electric Company, LLC.

The agenda for the subject meeting shall be as follows:

Tuesday, July 8, 2008—9 a.m.–5 p.m.

The Subcommittee will review the staff's safety evaluation associated with the Millstone Power Station Unit 3 stretch power uprate. The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, DNC, Westinghouse, and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Officer, Mr. David Bessette at 301–415–8065, five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 26, 2007, (72 FR 54695).

Further information regarding this meeting can be obtained by contacting the Designated Federal Official between 8:45 a.m. and 5:30 p.m. (ET). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes to the agenda.

Dated: June 23, 2008.

Antonio Dias,

Chief, Reactor Safety Branch B.

[FR Doc. E8–14595 Filed 6–26–08; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: [73 FR 35427, June 23, 2008].

STATUS: Closed Meeting.

PLACE: 100 F Street, NE., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Thursday, June 26, 2008 at 10 a.m.

CHANGE IN THE MEETING: Cancellation of Meeting.

The Closed Meeting scheduled for Thursday, June 26, 2008 has been cancelled.

For further information please contact the Office of the Secretary at (202) 551–5400.

June 24, 2008.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–14611 Filed 6–26–08; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58004; File No. SR–FINRA–2008–009]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving Proposed Rule Change to the Code of Arbitration Procedure for Customer Disputes and the Code of Arbitration Procedure for Industry Disputes To Amend the Chairperson Eligibility Requirements

June 23, 2008.

I. Introduction

On March 12, 2008, the Financial Industry Regulatory Authority, Inc. (''FINRA'') (f/k/a National Association of Securities Dealers, Inc. (''NASD'')) filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change relating to amendments to NASD Rule 12400(c) of the Code of Arbitration Procedure for Customer Disputes (''Customer Code'') and NASD Rule 13400(c) of the Code of Arbitration Procedure for Industry Disputes (''Industry Code''). The proposed rule change was published for comment in the **Federal Register** on March 25, 2008.[3] The Commission received five comment letters in response to the proposed rule change.[4] This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The proposed rule change amends the chairperson eligibility requirements under Rule 12400(c) of the Customer Code and Rule 13400(c) of the Industry Code.

On January 24, 2007, the SEC approved the Customer and Industry Codes (collectively referred to as

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–57529 (March 19, 2008); 73 FR 15817 (Mar. 25, 2008).

[4] *See* letter from Scot D. Bernstein, dated April 4, 2008 (''Bernstein letter''); letter from William A. Jacobson, Esq., Associate Clinical Professor, Director, Securities Law Clinic, Cornell Law School, dated April 15, 2008 (''Cornell letter''); letter from Lawrence S. Schultz, President, Public Investors Arbitration Association, dated April 16, 2008 (''PIABA letter''); letter from Karen Lockwood, dated May 12, 2008 (''Lockwood letter''); and letter from Barry D. Estell, Esquire, dated May 22, 2008 (''Estell letter'').

''Codes'').[5] The Codes reorganized the dispute resolution rules into separate procedural codes, simplified the language of the old NASD Code of Arbitration Procedure, codified current practices, and implemented several substantive changes. One such substantive change involved improving the arbitrator selection process by creating and maintaining a new roster of arbitrators who are qualified to serve as chairpersons.

Under the Codes, arbitrators are eligible for the chairperson roster if they have completed chairperson training provided by FINRA [6] or have substantially equivalent training or experience, and satisfy one of two remaining requirements of the rule.[7] In the rule filing proposing this change, FINRA explained that ''substantially equivalent training or experience would include service as a judge or administrative hearing officer, chairperson training offered by another recognized dispute resolution forum, or the like. Decisions regarding whether particular training or experience other than FINRA chairperson training would qualify under this provision would be in the sole discretion of the Director.'' [8] In referring to the ''substantially equivalent training or experience'' criterion (hereinafter, ''substantially equivalent''), the proposal also stated that FINRA believed that the proposal would allow arbitrators of all professional backgrounds to qualify as chairpersons.[9] FINRA believed that this criterion would help ensure that the forum could meet the demands of the Codes concerning the new chairperson roster, while allowing FINRA to continue to administer effectively the arbitrator selection process.

In the year since the Codes were approved, FINRA has determined that the ''substantially equivalent'' criterion has not been essential to creating and maintaining the chairperson roster, and therefore proposed to remove this criterion from the rule. FINRA notes that all arbitrators currently coded as chairpersons have completed the FINRA Chairperson Training course (chair training),[10] and the chair training has never been waived for an arbitrator claiming to satisfy the ''substantially equivalent'' criterion. FINRA believes that all arbitrators wishing to serve as chairpersons would benefit from the information contained in the chair training, which instructs arbitrators on the added responsibilities of arbitrators assuming the essential role of chairperson in the FINRA forum. Moreover, FINRA believes that removing the ''substantially equivalent'' criterion would make the chairperson eligibility standards more objective and uniform, thereby eliminating any perception that large numbers of arbitrators may be added to the chairperson roster without the benefit of the chair training.

III. Comment Letters

The Commission received five comment letters on the proposal.[11] Three commenters opposed the proposal;[12] one commenter urged the Commission to postpone taking final action on the proposed rule change pending further study;[13] and one commenter offered no opinion on the proposal.[14]

Two commenters argued that the amendments would further reduce the potential size of FINRA's pool of arbitrators who could be eligible to serve as chair by removing the ''substantially equivalent'' criterion from the rule.[15]

In a letter to the Commission, FINRA responded to these comments, stating that the proposal will not narrow the pool of arbitrators who could be eligible to serve as chair.[16] FINRA explained that, in the year since the Codes were approved, the substantially equivalent criterion has proved irrelevant to creating and maintaining the chairperson roster.[17] Further, FINRA explained that all arbitrators currently coded as chairpersons have completed the FINRA Chairperson Training course (chair training) and that FINRA has never waived the chair training for an arbitrator under the substantially equivalent criterion.[18] Finally, FINRA suggested that this criterion has had no impact on its ability to maintain or expand the chairperson roster, and is therefore not necessary.[19]

Three commenters contended that by removing the substantially equivalent criterion, FINRA would be, in effect, implementing a mandatory arbitrator training requirement, which would give FINRA undue control over the arbitrators who may serve as chairs.[20]

FINRA responded that the proposal would, instead, result in less staff discretion because staff would not be assessing the arbitrator's prior experience or training to determine whether it was substantially equivalent to FINRA chair training.[21] Under the proposal, arbitrators would be required to take FINRA's online chair training to become chair eligible. FINRA indicated that this requirement (which is easily measured) would make chair eligibility determinations more objective, because staff would not have to decide whether an arbitrator's experience meets the substantially equivalent threshold.[22] FINRA stated that it believes the proposed amendments to the chair eligibility standards are reasonable and, along with the rule's other criteria, will provide investors with access to well-trained and well-qualified arbitrators.[23]

One commenter suggested that chair training should not be a prerequisite to appointment as chair. [24] Rather, the commenter suggested that FINRA could require that arbitrators, appointed as chair, complete the training prior to the initial pre-hearing conference (IPHC).[25]

FINRA responded by stating that it has considered this suggestion, but concluded that it would be unworkable in its forum.[26] FINRA pointed out that there could be instances in which an arbitrator is appointed as chair, but does not want to serve as the chair, refuses to take the chair training, or delays taking the training and does not complete it by the time of the IPHC.[27] In such instances, FINRA explained, the case would be delayed while either the arbitrator is removed and another is appointed, or the IPHC is re-scheduled

[5] *See* Securities Exchange Act Release No. 55158 (January 24, 2007); 72 FR 4574 (January 31, 2007) (File Nos. SR–NASD–2003–158 and SR–NASD–2004–011). The new Codes became effective on April 16, 2007.

[6] Although some of the events referenced in this rule filing occurred prior to the formation of FINRA, the rule filing refers to FINRA throughout for simplicity.

[7] Rule 12400(c) of the Customer Code and Rule 13400(c) of the Industry Code.

[8] *See* Securities Exchange Act Release No. 51856 (June 15, 2005); 70 FR 36442, at 36446 (June 23, 2005).

[9] *Id.*

[10] The online Chairperson training course costs $50 and is available at *http://www.finra.org/ArbitrationMediation/ResourcesforArbitratorsandMediators/ArbitratorTraining/ArbitratorTrainingPrograms/index.htm* (last visited March 5, 2008).

[11] *See supra*, footnote 3.

[12] Bernstein, PIABA and Estell letters.

[13] Cornell letter.

[14] Lockwood letter.

[15] PIABA and Estell letters.

[16] *See* letter from Mignon McLemore, Assistant Chief Counsel, FINRA Dispute Resolution, dated June 2, 2008 (''FINRA letter'').

[17] FINRA letter.

[18] *Id.*

[19] *Id.*

[20] Bernstein, PIABA and Estell letters.

[21] FINRA letter.

[22] *Id.*

[23] *Id.*

[24] Cornell letter at footnote 2.

[25] Cornell letter. *See also* FINRA letter, footnote 10, stating that ''a pre-hearing conference is a hearing session that takes place before the hearing on the merits. Rule 12100(t) of the Customer Code and Rule 13100(t) of the Industry Code.''

[26] FINRA letter.

[27] *Id.*

to give the arbitrator additional time to take the training.[28] FINRA also stated that this suggestion would create a significant administrative burden on staff, as staff would be required to monitor continuously the arbitrators' training reports to ensure that they have completed the chair training prior to IPHCs.[29] For these reasons, FINRA declined to amend the proposal to implement this suggestion.[30]

One commenter requested that FINRA make available arbitrator selection records, beyond information publicly available from the Arbitration Awards Online database, so that it could be analyzed to determine whether arbitrators who award punitive or large compensatory awards are appointed to cases with less frequency due to strikes from industry parties, and whether the fragmentation of the random selection process through a chair-qualified slot exacerbates the problem.[31]

FINRA responded that its arbitrator selection records are proprietary and confidential.[32] FINRA explained, that the arbitrator selection records are generated during the resolution of a private matter between parties and contain the parties' confidential information, such as their striking and ranking choices.[33] Further, FINRA stated that it does not make this information available to the public because it could inhibit the parties' decisions during the arbitration process, which would compromise the integrity of the arbitration process.[34] For these reasons, FINRA declined to make this information available.[35]

Finally, four commenters objected to the existence of the separate chair roster.[36] FINRA stated that it is not proposing to amend the structure of its arbitrator rosters in this rule filing.[37] Further, FINRA noted that these same concerns were addressed by FINRA in connection with the proposal and adoption of the Codes,[38] and the changes to the arbitrator rosters were approved by the SEC.[39] FINRA stated that these comments are, therefore, outside the scope of the rule filing.[40]

IV. Discussion and Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and the rules and regulations thereunder that are applicable to a national securities association.[41] In particular, the Commission believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[42] because it would enhance the fairness and neutrality of FINRA's arbitration forum by making the chairperson eligibility rules more objective and uniform.

V. Conclusions

It Is Therefore Ordered, pursuant to section 19(b)(2) of the Act,[43] that the proposed rule change (SR–FINRA–2008–009) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[44]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–14568 Filed 6–26–08; 8:45 am]

BILLING CODE 8010–01–P

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] Cornell letter.

[32] FINRA letter.

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] Bernstein, Cornell, PIABA, and Estell letters.

[37] FINRA letter.

[38] *Id.* citing Response to Comments and Amendment No. 5, May 4, 2006 (File No. SR–NASD–2003–158), at 21–22; *see also* Response to Comments and Partial Amendment 7, August 15, 2006 (File No. SR–NASD–2003–158), at 8.

[39] FINRA letter.

[40] *Id.*

[41] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. *See* 15 U.S.C. 78c(f).

[42] 15 U.S.C. 78o–(b)(6).

[43] 15 U.S.C. 78s(b)(2).

[44] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58002; File No. SR–Phlx–2008–42]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Catastrophic Errors

June 23, 2008.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 17, 2008, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to adopt amendments to Exchange Rule 1092 (''Rule'') to: (i) Define a ''Catastrophic Error''; (ii) extend the time period for member notification to Exchange staff that the member believes it has participated in a trade that resulted from a Catastrophic Error; and (iii) state in the Rule that, if the parties to such a trade do not agree on an adjustment price, trades resulting from a Catastrophic Error will be adjusted to the Theoretical Price of the affected option series, plus or minus a pre-determined adjustment value, depending on the Theoretical Price of the series.

The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.phlx.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change, and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Phlx has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange states that the purpose of the proposed rule change is to help its members better manage risk by affording them relief from trades that result from a Catastrophic Error.

The proposed rule change would address particularly egregious options trading errors, called Catastrophic Errors. An Options Exchange Official[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Exchange Rules 124(a) and (b).

would determine that a Catastrophic Error occurred when the execution price of a transaction is higher or lower than the Theoretical Price for the series by an amount equal to at least the minimum amount shown below:

Theoretical price	Minimum amount
Below $2	$1
$2 to $5	2
Above $5 to $10	5
Above $10 to $50	10
Above $50 to $100	20
Above $100	30

The proposed rule change would also set forth the procedure to be followed when an Exchange member believes that he/she has participated in a trade resulting from a Catastrophic Error. Significantly, the time period within which such a member would be required to notify the Exchange's Market Surveillance staff that such an error may have occurred would be extended well beyond the time period applicable to an Obvious Error under current Phlx Rule 1092. Members would have until 8:30 a.m. Eastern Time on the first trading day following the date on which the Catastrophic Error occurred to make such a notification, except that for such transactions in an expiring options series that take place on an expiration day, an Exchange member must notify the Exchange by 5 p.m. Eastern Time that same day.

If it is determined that a Catastrophic Error has occurred, unless both (all) parties agree to adjust the transaction to a different price, the execution price(s) of the transaction(s) will be adjusted to the theoretical price: (i) Plus the adjustment value provided below for erroneous buy transactions; and (ii) minus the adjustment value provided for erroneous sell transactions, as described below:

Theoretical price	Adjustment value
Below $2	$1
$2 to $5	2
Above $5 to $10	3
Above $10 to $50	5
Above $50 to $100	7
Above $100	10

The Exchange believes that the proposed longer time period is appropriate to allow members to discover, and seek relief from, trading errors that result in extreme losses. At the same time, the Exchange believes that the proposed Minimum Amounts required for a trade to qualify as a Catastrophic Error, in combination with the large Adjustment Values, assures that only those transactions where the price of the execution results in very high losses will be eligible for adjustment under the new provisions. While the Exchange believes it is important to identify and resolve trading errors quickly, it also believes it is important to the integrity of the marketplace to have the authority to mitigate extreme losses resulting from errors.

A member that requests a review under the proposed rule would be charged $5,000 by the Exchange if there is no adjustment or nullification of the transaction. The initial ruling by the Options Exchange Official would be appealable to the Exchange's Referee.[6]

The Exchange states that it has weighed carefully the need to assure that one market participant is not permitted to receive a windfall at the expense of another market participant that made an Obvious Error, against the need to assure that market participants are not simply being given an opportunity to reconsider poor trading decisions. The Exchange states that, while it believes that the Obvious Error Rule strikes the correct balance in most situations, in some extreme situations, trade participants may not be aware of errors that result in very large losses within the time periods currently required under the rule. In this type of extreme situation, the Exchange believes its members should be given more time to seek relief so that there is a greater opportunity to mitigate very large losses and reduce the corresponding large wind-falls. However, to maintain the appropriate balance, the Exchange believes members should only be given more time when the execution price is much further away from the theoretical price than is required for Obvious Errors so that relief is only provided in extreme circumstances.[7]

Under the proposed rule, members will have until 8:30 a.m. Eastern Time on the trading day following the trade to notify the Exchange of a potential Catastrophic Error. For trades that take place in an expiring series on the day of expiration, members must notify the Exchange's Market Surveillance Department of a potential Catastrophic Error by 5 p.m. Eastern Time that same day. Once a member has notified Market Surveillance of a potential Catastrophic Error, within the required time period, an Options Exchange Official would review and make a determination as to the claim.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[8] in general, and furthers the objectives of section 6(b)(5) of the Act,[9] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by helping Exchange members better manage risk through the Catastrophic Error rule. In particular, the proposal would allow members a longer opportunity to seek relief from errors that result in large losses.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of filing (or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest), the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act[10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing.[12] However, Rule 19b–4(f)(6)(iii) permits the Commission to

[6] *See* Exchange Rule 124, Commentary .02 and current Exchange Rule 1092(f).

[7] The Exchange does not believe the type of extreme situation that is covered by the proposed rule would occur in the normal course of trading. Rather, this type of situation could potentially occur as a result of, for example, an error in a member's quotation system that causes a market maker to severely misprice an option.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii). The Exchange has satisfied the five-day pre-filing requirement of Rule 19b–4(f)(6)(iii).

designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay and designate the proposed rule change operative upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Given that the Exchange's proposed catastrophic error rule is substantially similar to that of the International Securities Exchange and that of NYSE Arca,[13] the proposal does not appear to present any novel regulatory issues. Therefore, the Commission designates the proposal operative upon filing.[14]

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 the furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2008–42 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2008–42. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2008–42 and should be submitted on or before July 18, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–14566 Filed 6–26–08; 8:45 am]

BILLING CODE 8010–01–P

[13] *See* Securities Exchange Act Release Nos. 57398 (February 28, 2008), 73 FR 12240 (March 6, 2008) (SR–ISE–2007–112) and 57653 (April 11, 2008), 73 FR 20996 (April 17, 2008) (SR–NYSEArca–2008–41).

[14] For purposes only of waiving the operative delay of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 6279]

Culturally Significant Objects Imported for Exhibition Determinations: ''Giorgio Morandi, 1890–1964''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236 of October 19, 1999, as amended, and Delegation of Authority No. 257 of April 15, 2003 [68 FR 19875], I hereby determine that the objects to be included in the exhibition ''Giorgio Morandi, 1890–1964'' to be displayed at The Metropolitan Museum of Art, New York, New York, imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about September 16, 2008, until on or about December 14, 2008, and at possible additional exhibitions or venues yet to be determined, is in the national interest. Public Notice of these Determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Wolodymyr Sulzynsky, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (*telephone:* 202/453–8050). The address is U.S. Department of State, SA–44, 301 4th Street, SW., Room 700, Washington, DC 20547–0001.

Dated: June 20, 2008.

C. Miller Crouch,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. E8–14637 Filed 6–26–08; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 6278]

Culturally Significant Objects Imported for Exhibition Determinations: ''Hearst the Collector''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236 of October 19, 1999, as amended, and Delegation of Authority No. 257 of April 15, 2003 [68 FR 19875], I hereby determine that the objects to be included in the exhibition ''Hearst the Collector'', imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Los Angeles County Museum of Art, Los Angeles, California, from on or about November 9, 2008, until on or about February 1, 2009, and at possible additional exhibitions or venues yet to be determined, is in the national interest. Public Notice of these

Determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Richard Lahne, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (*telephone:* 202–453–8058). The address is U.S. Department of State, SA–44, 301 4th Street, SW., Room 700, Washington, DC 20547–0001.

Dated: June 20, 2008.

C. Miller Crouch,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. E8–14636 Filed 6–26–08; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highways in Alaska

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to various proposed highway projects in the State of Alaska. Those actions grant approvals for the projects.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the listed highway project will be barred unless the claim is filed on or before *December 24, 2008.* If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Mr. Michael E. Vanderhoof, Environmental Coordinator, FHWA Alaska Division, P.O. Box 21648, Juneau, Alaska 99802–1648; office hours 8 a.m.–4 p.m. (AST), phone (907) 586–7418; e-mail *michael.vanderhoof@fhwa.dot.gov.* You may also contact Jerry O. Ruehle, DOT&PF Central Region Environmental Manager, Alaska Department of Transportation and Public Facilities, 4111 Aviation Drive, P.O. Box 196900, Anchorage, Alaska 99519–6900; office hours 7:30 a.m.—5 p.m. (AST), phone (907) 269–0534, e-mail *Jerry_Ruehle@dot.state.ak.us.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA has taken final agency actions by issuing approvals for the following highway project in the State of Alaska that is listed below. The actions by the Federal agency on the project, and the laws under which such actions were taken, are described in the Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) issued in connection with the project. The EA, FONSI, and other documents from the FHWA administrative record files for the listed project is available by contacting the FHWA or the State of Alaska Department of Transportation & Public Facilities at the addresses provided above. EA and FONSI documents can be viewed and downloaded from the project Web site at *http://www.dowlingroad.com* or viewed at 4111 Aviation Avenue, Anchorage, Alaska 99519.

This notice applies to all FHWA decisions and approvals on the listed project as of the issuance date of this notice and all laws and Executive Orders under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Air:* Clean Air Act, [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].

4. *Wildlife:* Endangered Species Act of 1973 [16 U.S.C. 1531–1544 and Section 1536]; Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(g)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act 1976 as amended [16 U.S.C. 1801 *et seq.*].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1251–1377]; Coastal Zone Management Act [16 U.S.C. 1451–1465]; Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287].

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 13186 Migratory Birds; E.O. 11514 Protection and Enhancement of Environmental Quality.

The project subject to this notice is:

Project: West Dowling Road Connection Project. *Project Location:* Anchorage, Alaska, Municipality of Anchorage, West Dowling Road. Project Reference Number: STP–0532(5) Project type: Road improvements and extension of Dowling Road between Old Seward Highway and Minnesota Drive, a distance of approximately 1.65 miles. The Dowling Road arterial will be extended from B Street to Minnesota Drive and will be widened to 5 lanes between Old Seward Highway and B Street with associated improvements to railroad crossings, traffic control, lighting, drainage, noise barriers, bridges, and trails. These improvements are needed to address current and future connectivity and accessibility needs and to address the need for an east-west arterial between Tudor Road and Dimond Boulevard as outlined in the Anchorage Bowl Long Range Transportation Plan. NEPA document: An EA and FONSI were approved on April 1, 2008, and are available electronically at *http://www.dowlingroad.com.*

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1)

David C. Miller,

Division Administrator, Juneau, Alaska.

[FR Doc. E8–13636 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2008–0009, Notice No. 2]

Declaration of Emergency Event

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Notice of declaration of emergency event.

SUMMARY: On June 11, 2008, the Administrator of the FRA determined that the recent flooding around the Midwest region of the United States

constituted an emergency event as related to railroad operations. Accordingly, the Administrator activated the Emergency Relief Docket. This document provides notice of the Administrator's determination.

SUPPLEMENTARY INFORMATION: On June 11, 2008, the Administrator of the FRA determined that the recent flooding around the Midwest region of the United States constituted an emergency event pursuant to 49 CFR 211.45(c) and that public safety would benefit from providing the railroad industry with operational relief directly related to that emergency. Accordingly, the Administrator activated the Emergency Relief Docket (docket number FRA–2008–0009) and in accordance with 49 CFR 211.45(g), petitions received in that docket pursuant to this emergency event will be handled according to the requirements of 49 CFR 211.45(g)–(j).

Interested parties are reminded that the procedures in 49 CFR 211.45 provide for expedited review and processing of emergency waiver petitions. Accordingly, in accordance with 49 CFR 211.45(h), any person wishing to comment on petitions for emergency waivers should submit their comments to the docket within 72 hours from the close of business on the day that the petition is posted in the public docket. Any person desiring a public hearing on any petition being processed in accordance with the emergency waiver procedures must notify FRA of such request in their comments submitted to the docket. 49 CFR 211.45(i).

Interested persons may submit their comments using any of the following methods:

(1) E-mail to FRA at *RRS.Correspondence@dot.gov;*

(2) Fax to FRA at: 202–493–6309; or

(3) Hand deliver or expedited delivery to the Docket Clerk, Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590 or electronically via the Internet at *http://www.regulations.gov.*

All communications concerning any petition in the Emergency Relief Docket should identify the appropriate docket number (e.g., FRA–2008–0009).

Privacy

Anyone is able to search all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 665, Number 7, Pages 19477–78). The statement may also be found at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on June 23, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–14542 Filed 6–26–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–290 (Sub–No. 290X)]

Norfolk Southern Railway Company—Abandonment Exemption—in Lucas County, OH

Norfolk Southern Railway Company (NSR) has filed a verified notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon a 2.82-mile line of railroad between milepost TW 0.00 and milepost TW 2.82 in Toledo, Lucas County, OH.[1] The line traverses United States Postal Service Zip Codes 43604, 43607, and 43609.

NSR has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) overhead traffic on the line, if any, has been rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on July 29, 2008, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by July 7, 2008. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by July 17, 2008,[4] with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to NSR's representative: James R. Paschall, Senior General Attorney, Norfolk Southern Corporation, Three Commercial Place, Norfolk, VA 23510.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

NSR has filed environmental and historic reports that address the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by July 3, 2008. Interested persons may obtain a copy of the EA by writing to SEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 245–0305. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.] Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

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[1] In Docket No. AB–290 (Sub–No. 39X), *Norfolk and Western Railway Company—Discontinuance Exemption—Operations between Toledo and Walbridge Junction, OH,* the Interstate Commerce Commission granted authority for Norfolk and Western Railway Company (NW) to discontinue its service over the line. In its notice here, however, NSR, as successor to NW by merger, indicates that the portion of its line between milepost TW 2.69 and milepost TW 2.82 shares the right-of-way and a bridge with an active rail line, and NSR states that no salvage or other track removal activities will occur on that segment and that the bridge will be unaffected.

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C. 2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Each OFA must be accompanied by the filing fee, which currently is set at $1,300. *See* 49 CFR 1002.2(f)(25).

[4] NSR states that it does not have fee title to the entire right-of-way underlying the line and will not have a contiguous corridor available for public use.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), NSR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by NSR's filing of a notice of consummation by June 27, 2009, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at ''*http://www.stb.dot.gov.*''

Decided: June 23, 2008.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–14577 Filed 6–26–08; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Ex Parte No. 677 (Sub–No. 1)]

Common Carrier Obligation of Railroads—Transportation of Hazardous Materials

AGENCY: Surface Transportation Board.

ACTION: Notice of Rescheduled Hearing.

SUMMARY: The Surface Transportation Board (Board) hereby gives notice of the rescheduling of its hearing regarding the common carrier obligation of railroads with respect to the transportation of hazardous materials.

DATES: The public hearing will take place on Tuesday, July 22, 2008 at 9 a.m.. Any person wishing to speak at the hearing should file with the Board a written notice of intent to participate, and should identify the party, the proposed speaker, and the time requested, as soon as possible but no later than July 10, 2008. Each speaker should also file with the Board his/her written testimony in that same document. Written submissions by interested persons who do not wish to appear at the hearing will also be due by July 10, 2008.

FOR FURTHER INFORMATION CONTACT: Timothy Strafford 202–245–0356. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: By a decision served on June 4, 2008, the Board announced that it would hold a hearing at 9 a.m. on Wednesday, July 16, 2008, at its headquarters in Washington, DC, for the purpose of examining issues related to the common carrier obligation of railroads with respect to the transportation of hazardous materials. Persons wishing to speak at the hearing were directed to notify the Board in writing and submit their written testimony no later than July 2, 2008. Written testimony from other interested parties was also due by July 2, 2008.

In order to address witness availability concerns, the Board served a decision on June 19, 2008, announcing that it would grant a short extension and hold the hearing on Tuesday, July 22, 2008. The hearing will begin at 9 a.m. in the 1st floor hearing room at the Board's headquarters at 395 E Street, SW., in Washington, DC, and will continue, with short breaks if necessary, until every person scheduled to speak has been heard. In light of the Independence Day holiday, the Board announced by decision served June 23, 2008 that it would extend the due date for notices of intent to participate and written testimony by hearing participants, as well as other interested persons who do not wish to appear at the hearing, until July 10, 2008.

Board Releases and Live Video Streaming Available Via the Internet. Decisions and notices of the Board are available on the Board's Web site at ''*http://www.stb.dot.gov.*'' This hearing will be available on the Board's Web site by live video streaming. To access the hearing, click on the ''Live Video'' link under ''Information Center'' at the left side of the home page beginning at 9 a.m. on July 22, 2008.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Dated: June 23, 2008.

By the Board, Anne K. Quinlan, Acting Secretary.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–14574 Filed 6–26–08; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 35147 [1]]

Norfolk Southern Railway Company, Pan Am Railways, Inc., et al.—Joint Control and Operating/Pooling Agreements—Pan Am Southern, LLC

AGENCY: Surface Transportation Board.

ACTION: Decision No. 2 in STB Finance Docket No. 35147; Notice of Acceptance of Primary Application and Related Filings; Issuance of Procedural Schedule.

SUMMARY: The Surface Transportation Board (Board) is accepting for consideration the primary application and related filings, filed on May 30, 2008, by Norfolk Southern Railway Company (Norfolk Southern), Pan Am Railways, Inc. (PARI) (a noncarrier railroad holding company), and two of PARI's rail carrier subsidiaries, Boston and Maine Corporation (B&M) and Springfield Terminal Railway Company (Springfield Terminal) (collectively, Applicants). The primary application seeks Board approval under 49 U.S.C. 11322 and 11323 of (1) the acquisition by Norfolk Southern and B&M of joint control and ownership of Pan Am Southern, LLC (PAS), a new rail carrier to be formed; and (2) the agreements by which Springfield Terminal would operate the lines of PAS and establish rates for PAS. The agreements for which approval and authorization are being sought by the application and the related filings will be referred to collectively as the Transaction.

If the Transaction is approved, PAS would own or operate over (through trackage rights) approximately 437 miles of track (PAS Lines). The PAS Lines consist of 238.3 miles of rail lines to be owned by PAS, as well as 198.4 miles of track over which PAS would have trackage rights. The west to east main line section of the PAS Line, called the Patriot Corridor, would be comprised of 139.7 miles of track to be owned by PAS extending from Mechanicville, NY to CPF–312, near Ayer, MA, as well as 15.8 miles of trackage rights over Massachusetts Bay Transportation Authority (MBTA) track between Fitchburg, MA and Willows, MA. The north-south section of the PAS Lines extending from White River Junction, VT to New Haven, CT would be comprised of: (1) 72.8 miles of trackage rights over New England Central Railroad (NECR) between White River Junction, VT and East Northfield, MA; (2) 49.7 miles of track to be owned by PAS on the Connecticut River Mainline between East Northfield, MA and Springfield, MA; and (3) 62.0 miles of

[1] This decision also embraces *Pan Am Southern, LLC—Acquisition and Operation Exemption—Lines of Boston and Maine Corporation*, STB Finance Docket No. 35147 (Sub-No. 1); *Norfolk Southern Railway Company—Trackage Rights Exemption—Pan Am Southern, LLC—Between Mechanicville, NY and Ayer, MA*, STB Finance Docket No. 35147 (Sub-No. 2); and *Springfield Terminal Railway Company—Trackage Rights Exemption—Pan Am Southern, LLC—Between CPF 312 Near Willows, MA, and Harvard Station, MA*, STB Finance Docket No. 35147 (Sub-No. 3) (collectively, the related filings).

trackage rights over the National Railroad Passenger Corporation (Amtrak) between Springfield, MA and New Haven, CT. The PAS Lines would also include several branch lines.[2]

In addition, the parties have filed with the application three related notices of exemption. Pursuant to 49 CFR 1150.35(a), the first is a notice of intention to file, on or after June 16, 2008, a notice of exemption in *Pan Am Southern, LLC—Acquisition and Operation Exemption—Lines of Boston and Maine Corporation,* STB Finance Docket No. 35147 (Sub-No. 1), for PAS to acquire from B&M the 437 miles of rail lines and trackage rights involved in the Transaction and to operate over the lines as a common carrier. The second is a notice of exemption in *Norfolk Southern Railway Company—Trackage Rights Exemption—Pan Am Southern, LLC—Between Mechanicville, NY and Ayer, MA,* STB Finance Docket No. 35147 (Sub-No. 2), for Norfolk Southern to acquire trackage rights over 151.33 miles of PAS track between Mechanicville, NY and Ayer, MA. Finally, Applicants have included a notice of exemption in *Springfield Terminal Railway Company—Trackage Rights Exemption—Pan Am Southern, LLC—Between CPF 312 Near Willows, MA, and Harvard Station, MA,* STB Finance Docket No. 35141 (Sub-No. 3), for Springfield Terminal to acquire trackage rights over 6.4 miles of PAS track, to allow Springfield Terminal to continue to connect its remaining lines and to preserve connections to CSXT and Providence and Worcester Railroad Company (P&W).

In this decision, the Board finds that the Transaction is a ''minor transaction'' under 49 CFR 1180.2(c). The Board also adopts a procedural schedule for consideration of the application under which the Board's final decision would be issued on October 20, 2008, and become effective on November 4, 2008, assuming that there is no need for further environmental analysis. *See* the discussion on environmental matters, below.

DATES: The effective date of this decision is June 27, 2008. Comments on applicants' Environmental Appendix, which sets out why they believe no formal environmental review is warranted in this case, are due to the Board's Section of Environmental Analysis (SEA) by July 7, 2008. Any person who wishes to participate in this proceeding as a party of record (POR) must file, no later than July 11, 2008, a notice of intent to participate. All comments, protests, requests for conditions, and any other evidence and argument in opposition to the primary application and related filings, including filings by the U.S. Department of Justice (DOJ) and the U.S. Department of Transportation (DOT), must be filed by August 11, 2008. Responses to comments, protests, requests for conditions, and other opposition, and rebuttal in support of the primary application or related filings must be filed by September 5, 2008. If a public hearing or oral argument is held, it will be held on a date to be determined by the Board. The Board will issue its final decision on October 20, 2008, unless an extension is needed to permit the completion of formal environmental review.

ADDRESSES: Any filing submitted in this proceeding must be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions found on the Board's Web site at *www.stb.dot.gov* at the ''E–FILING'' link. Any person submitting a filing in the traditional paper format should send an original and 10 paper copies of the filing (and also an electronic version) to: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, one copy of each filing in this proceeding must be sent (and may be sent by e-mail only if service by e-mail is acceptable to the recipient) to each of the following: (1) Secretary of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590; (2) Attorney General of the United States, c/o Assistant Attorney General, Antitrust Division, Room 3109, Department of Justice, Washington, DC 20530; (3) Richard A. Allen (representing Applicants), Zuckert, Scoutt & Rasenberger, LLP, 888 Seventeenth Street, N.W., Suite 700, Washington, DC 20006; and (4) any other person designated as a POR on the service list notice (as explained below, the service list notice will be issued as soon after July 11, 2008, as practicable).

FOR FURTHER INFORMATION CONTACT: Julia M. Farr, (202) 245–0359. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Norfolk Southern is a Class I railroad headquartered in Norfolk, VA. With more than 30,000 employees, it operates approximately 21,000 route miles in 22 states and the District of Columbia. Norfolk Southern is a wholly owned subsidiary of Norfolk Southern Corporation, a publicly held noncarrier holding company. Norfolk Southern provides intermodal rail service to upstate New York, New England and Canada through haulage agreements with CP (including CP subsidiaries) (collectively, CP) and Springfield Terminal.[3]

Springfield Terminal is a Class II rail carrier. Its principal office, and that of its affiliate, B&M, is in Massachusetts. With approximately 700 employees, Springfield Terminal operates some 2,056 route miles in Maine, New Hampshire, Vermont, Massachusetts, New York, and Connecticut.

PARI is a noncarrier holding company formerly known as Guilford Transportation Industries, Inc. (GTI). PARI has four wholly owned subsidiaries, including B&M and Springfield Terminal. PARI (then GTI) acquired Maine Central Railroad, Inc. (MCR) in 1981, and in 1983, it purchased B&M and Springfield Terminal. Springfield Terminal's lines extend from Rotterdam Junction, NY in the west, to Mattawamkeag, ME in the east and, with trackage rights, to New Haven, CT in the south.[4] Springfield Terminal interchanges traffic with 15 other railroads. In addition to interchanges with 11 short lines, Springfield Terminal interchanges with CSXT at Rotterdam Junction, NY, Hartford CT,[5] Holyoke, MA, Barbers,

[2] The branch lines consist of: (1) The Rotterdam Branch, which is approximately 30.5 miles between Rotterdam Junction, NY and Mechanicville, NY (including 18.3 miles of trackage over Canadian Pacific Railway Company (CP) between Mohawk Yard in Schenectady, NY and Mechanicville, NY); (2) the Adams Industrial branch, which is approximately 4.6 miles between N. Adams, MA and Adams, MA; (3) the Heywood Industrial branch, which is approximately 1.2 miles between Gardner, MA and Heywood, MA; (4) approximately 2.3 miles between Ayer, MA and Harvard Station, MA; (5) the Groton Industrial, which consists of trackage rights over MBTA extending approximately 5 miles between Ayer, MA and Groton, MA; (6) approximately 2.3 miles of trackage rights over MBTA between Willows, just east of Ayer, MA, and Littleton, MA; (7) approximately 42.9 miles between Berlin, CT and Derby, CT (including 18.6 miles of trackage rights over Metro North Commuter Railroad (MNCR) between Waterbury, CT and Derby, CT); (8) the Southington Industrial branch, which is approximately 4.5 miles between Plainville, CT and Southington, CT; and (9) approximately 3.7 miles of trackage rights over CSX Transportation, Inc. (CSXT) between North Haven, CT and Cedar Hill, CT.

[3] CP provides haulage of intermodal traffic to Norfolk Southern over a CP line from Sunbury, PA to Mechanicville, NY, and Springfield Terminal provides haulage of intermodal traffic to Norfolk Southern over its line from Mechanicville to the intermodal terminals in Ayer, MA and Waterville, ME.

[4] In 1984, GTI also acquired the Delaware & Hudson Railway Company (D&H). D&H filed for bankruptcy protection in 1988 and is now owned by CP.

[5] The Hartford interchange point with CSXT is currently inactive.

MA, Clinton, MA, and Boston, MA (I and F Junction); with CP at CP's Mohawk Yard in Schenectady, NY, St. Johnsbury, VT, and Wells River, VT; with Norfolk Southern at Mohawk Yard; [6] and with Canadian National Railway Company (CN) at Danville Junction, ME, and St. John, New Brunswick (via CN haulage rights). The largest source of Springfield Terminal's traffic is the paper industry, for which Springfield Terminal transports inbound chemicals, clay, and pulp, and outbound paper.

Norfolk Southern, PARI, B&M and Springfield Terminal entered into a Transaction Agreement dated May 15, 2008, which would require the parties upon closing to establish PAS and to effect various other agreements (Ancillary Agreements), the complete versions of which are attached to the confidential version of the application filed with the Board. The Transaction Agreement is subject to, and would be consummated following, receipt of Board approval and effectiveness of applicable exemptions. The Transaction Agreement requires Norfolk Southern to contribute $137.5 million in cash and demand notes, and to assign a Purchase Option [7] to PAS for which Norfolk Southern would receive a 50% membership interest in PAS. The Transaction Agreement requires the Pan Am parties to contribute a 73.684% undivided interest in the PAS Lines, certain trackage rights, and other related assets to PAS for which B&M would receive a 50% membership interest in PAS, and for PAS to use $47.5 million of its capital to exercise the Purchase Option contributed by Norfolk Southern and purchase the other 26.316% undivided interest in the PAS Lines, certain trackage rights, and other related assets from the Pan Am parties.

The application states that Norfolk Southern would infuse substantial capital into PAS, $87.5 million dollars of which would go into improving infrastructure. PAS would use part of that capital to remove long term slow orders along the Patriot Corridor and add capacity and clearances along that line for better traffic flow. Springfield Terminal would provide the labor associated with these capital projects, to the same extent it would do so under its operation of these lines today under its collective bargaining agreements.

According to the application, PAS would use a portion of the capital contributed by Norfolk Southern to create the Mechanicville Facility. The proposed Mechanicville Facility is expected to significantly improve overhead rail operations for intermodal and automotive traffic destined to Ayer, MA. The existing intermodal facility at Ayer also would be improved, and a new automotive facility would be constructed at San Vel near Ayer (San Vel Automotive). According to Applicants, for traffic moving into the Boston area from the west, the Transaction would strengthen the existing Norfolk Southern/Springfield Terminal competitive option to CSXT's single line service because it makes PAS a more efficient competitor.

Applicants state that short line and regional railroads in the area—P&W, NECR, and Vermont Railroad, Inc. (VTR)—would not only interchange traffic with PAS, but would also obtain new direct routing opportunities for interchange with Norfolk Southern. According to Applicants, these railroads and their customers would benefit further from the proposed infrastructure improvements.

Passenger Service Impacts. According to Applicants, there are no passenger trains currently operating or expected to operate over the line segments proposed to be owned by PAS.

Discontinuances/Abandonments. Applicants state that the Transaction would not entail any abandonments or elimination of any facilities.

Financial Arrangements. According to Applicants, no new securities would be issued in connection with the Transaction, and Norfolk Southern's contribution to PAS would be funded from available cash and credit facilities. Norfolk Southern does not expect any increase in fixed charges as a result of the Transaction.

Time Schedule for Consummation. Applicants expect to consummate the Transaction promptly after the effective date of any Board approval of the Transaction.

Public Interest Considerations. Applicants contend that the Transaction would have no adverse competitive effects and that it would in fact enhance their ability to compete with trucks and with other railroads, most notably, CSXT, which is the only Class I railroad now providing rail service over its own lines to locations in this New England region. In a verified statement attached to the application, the Applicants' outside consultant maintains that: (1) The Transaction is an end-to-end transaction that would eliminate no competing routes, stations, or services; (2) no rail customer would be left with reduced competitive rail options as a result of the proposed transaction; and (3) the Transaction would not have any material adverse effects on connecting short lines, but would in fact benefit these carriers.

Applicants maintain that the improvement in their ability to compete would be most significant with respect to intermodal and automotive traffic between Massachusetts, eastern New York, and points west. Today, according to Applicants, CSXT has large intermodal and automotive terminals in eastern New York and Massachusetts and carries a large share of the intermodal and automotive traffic in those areas.[8] Applicants maintain that, with the improvements to the PAS Lines and the new or improved terminals at Ayer, San Vel and Mechanicville, Applicants' ability to expand their intermodal and automotive services into markets now largely dominated by CSXT would be significantly enhanced.

Applicants state that, in addition to furthering competition, the Transaction would further the public interest in meeting significant transportation needs. According to Applicants, the principal purpose of the Transaction is to enhance the existing infrastructure of the lines to be acquired by PAS, substantially improving service to rail customers. Infrastructure would be enhanced by: (1) Upgrading the lines to permit heavier (286,000 pound) rail cars, which are more efficient and economical for the coal-burning electric utilities served by the lines; (2) the proposed intermodal facility at Mechanicville, which would enable Norfolk Southern to better utilize its existing authority to move more efficient double-stack cars to eastern New York from points west and to move

[6] Norfolk Southern has the right to interchange traffic with Springfield Terminal at Mechanicville, NY, but the interchange now takes place by agreement at CP's Mohawk Yard. Following the Transaction and the construction of the proposed intermodal and automotive facility, to be located on the site of two former rail yards at Mechanicville, NY (Mechanicville Facility), it is anticipated that the interchange between Norfolk Southern and PAS will occur at that proposed facility. CP has consented to the relocation of its mainline and modification of the interchange location, in each case to accommodate the proposed Mechanicville Facility.

[7] Norfolk Southern has purchased an option (the Purchase Option) from B&M to purchase a 26.316% undivided interest in the PAS Lines and related assets for $52 million, and PARI has agreed to expend $2.5 million to perform specified track work. The $5 million option price paid by Norfolk Southern is non-refundable but will be credited against the purchase price when PAS exercises the Purchase Option at closing of the Transaction Agreement.

[8] According to Applicants, CSXT also leases a large terminal facility from Pan Am in Ayer, MA that is capable of handling automotive traffic, but CSXT has elected not to use it and not to relinquish the lease. B&M would contribute that facility to PAS, but it would not be available for PAS's use until 2017 due to the CSXT lease.

single-stack intermodal trains faster and more efficiently to eastern Massachusetts; and (3) the proposed automotive facilities at Mechanicville and San Vel, which are intended to improve service to shippers of automobiles to eastern New York and New England.

According to Applicants, the investment that Norfolk Southern would make in PAS would benefit not only coal, automotive, and intermodal customers but all Springfield Terminal and Norfolk Southern industrial customers. Applicants state that elimination of the interchange of intermodal traffic at the less efficient Mohawk Yard should improve the movement of all traffic through this area. Applicants also assert that customers that can utilize 286,000 pound rail cars would benefit from the rail and track improvements. Finally, according to Applicants, the capacity that would be added and the increase in the speed of the main line between Albany and Ayer would improve the fluidity, speed, and consistency of shipments for all customers using the services of PAS. The Transaction does not contemplate the elimination of any existing facilities.

According to Applicants, the short line and regional railroads that would connect with PAS and their customers, including particularly, VTR, P&W, and NECR, would likewise benefit from the improved service over the PAS Lines resulting from those investments, as well as from the new direct connections with Norfolk Southern.

Environmental Impacts. Applicants state that their representatives met with representatives of the Board's Section of Environmental Analysis (SEA) on April 22, 2008, to explain why, in Applicants' view, the Transaction would not have significant environmental impacts and require formal environmental review. At SEA's request and to assist the Board in determining whether a formal environmental review should be conducted, Applicants, on June 6, 2008, filed an Environmental Appendix in support of their position and asked for public comments on it. In their Environmental Appendix, Applicants maintain that the Transaction would not have significant environmental impacts because it would not cause significant changes in railroad operations and that further environmental review is not warranted.

Labor Impacts. Applicants expect that the Transaction would result in no adverse effect on any of the Applicants' employees. Employees of Springfield Terminal are currently providing all of the rail services over the PAS Lines. The Transaction Agreement and the Railroad Operating Agreement (attached to the application) state that, after consummation of the Transaction, Springfield Terminal would become the contract operator of the PAS Lines, and Springfield Terminal would be required to ''act in accordance with its then-current collective bargaining agreements as if the Assets were an integral part of the Springfield Terminal railroad network.'' [9] Applicants state that the Capital Facilities and Management Agreement (attached to the application) provides that Springfield Terminal would perform work on any capital contract that its labor agreements would require Springfield Terminal employees to perform under pre-Transaction circumstances unless Springfield Terminal obtains a waiver of any such requirement. Thus, according to Applicants, the same employees would be performing the same work under the same agreements for the foreseeable future.

In any event, Applicants expect that, as required by 49 U.S.C. 11326(a), the Board would impose the labor protective conditions set forth in *New York Dock Ry.—Control—Brooklyn Eastern Dist.,* 360 I.C.C. 60, 84–90 (1979) (*New York Dock), aff'd sub nom. New York Dock Ry.* v. *United States,* 609 F.2d 83 (2d Cir. 1979), on the elements of the Transaction that are subject to 49 U.S.C. 11323.

Related Filings. In connection with the Transaction, three notices of exemption were filed:

(Sub-No. 1). Pursuant to 49 CFR 1150.35(a), PAS filed a notice of intent to file, on or after June 16, 2008, a notice of exemption docketed as (Sub-No. 1), whereby PAS would acquire and operate certain lines of B&M and acquire incidental trackage rights from Springfield Terminal to operate over the lines of third parties. Pursuant to the primary application to which this notice in (Sub-No. 1) is related, PAS would be formed and Norfolk Southern would contribute cash, demand notes and the Purchase Option agreement to PAS, which together are valued at $140 million. Under the Transaction that is the subject of the notice in (Sub-No. 1), B&M would contribute certain railroad lines in Massachusetts, New York, Vermont, New Hampshire and Connecticut, totaling approximately 238 route miles. Springfield Terminal would assign to PAS trackage rights Springfield Terminal currently holds over certain lines of MBTA, NECR, CP, Amtrak, CSXT, and MNCR, totaling approximately 198 route miles.

(Sub-No. 2). Pursuant to 49 CFR 1180.2(d)(7) and 1180.4(g), Norfolk Southern filed a notice of exemption to permit it to acquire overhead trackage rights over approximately 151.33 miles of track that would be owned or operated by PAS between Mechanicville, NY and Ayer, MA. According to Norfolk Southern, the trackage rights that are the subject of this notice would enable Norfolk Southern to provide direct rail transportation of intermodal traffic to and from the existing intermodal terminal at Ayer, MA, and the new automotive terminal that the Applicants propose to construct at nearby San Vel, MA, in the event that PAS fails to provide haulage services at a service level required under the Transaction Agreement. Norfolk Southern would not exercise any of the trackage rights until the later of (1) the effective date of the notice of exemption (including compliance with any conditions imposed on the exemption by the Board) or (2) the closing of the agreements for which the Board's approval is being sought in the primary application. As a condition to this exemption, Applicants state that any employees affected by the acquisition of these trackage rights would be protected under the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN,* 354 I.C.C. 605 (1978), *as modified in Mendocino Coast Ry., Inc.—Lease and Operate,* 360 I.C.C. 653 (1980) *(N&W).*

(Sub No. 3). Pursuant to 49 CFR 1180.2(d)(7) and 1180.4(g), Springfield Terminal filed a notice of exemption to permit it to acquire overhead trackage rights over approximately 6.4 miles of track that would be owned by PAS between Willows, MA, and Harvard Station, MA. The trackage rights that are the subject of this notice would enable Springfield Terminal to provide direct transportation of traffic for its own account between its current lines east of CPF 312 and its current line south of Harvard Station, MA. These trackage rights also would enable Springfield Terminal to continue to interchange traffic in its own account directly with CSXT and the P&W at points south of Harvard Station. Springfield Terminal would not exercise any of the trackage rights until the later of (1) the effective date of the notice of exemption (including compliance with any conditions imposed on the exemption by the Board) or (2) the closing of the agreements for which the Board's approval is being sought in the primary application. As a condition to this exemption, Applicants state than any

[9] Exhibit E, Section 9(f)(ii)(A).

employees affected by the acquisition of these trackage rights would be protected under the conditions imposed in *N&W.*

Primary Application and Related Filings Accepted. Based on the information provided in the application, the Board finds the proposed Transaction to be a ''minor transaction'' under 49 CFR 1180.2(c). A transaction that does not involve two or more Class I railroads is minor if (1) it would clearly not have anticompetitive effects, or (2) any anticompetitive effects would clearly be outweighed by the transaction's contribution to the public interest in meeting significant transportation needs. On the face of the application, there does not appear to be a likelihood of any anticompetitive effects resulting from the Transaction. The Norfolk Southern and Pan Am systems are entirely end-to-end, and it appears that no shipper would have fewer competitive rail alternatives as a result of the Transaction.

The Transaction also would not appear to have an adverse competitive effect on connecting short line and regional carriers. The Transaction would not impose any interchange restrictions on PAS, and PAS would honor all of the existing interchange contracts with connecting carriers. Eight short lines connect with the Pan Am lines that would become part of the PAS Lines, and none would lose a connecting alternative as a result of the Transaction. Many short lines would simply be served by PAS instead of Pan Am, and some would gain more direct access to Norfolk Southern via PAS.

The Board's finding regarding competitive impact is preliminary. The Board will give careful consideration to any claims that the Transaction would have anticompetitive effects that are not apparent from the application itself.

The Board accepts the primary application for consideration because it is in substantial compliance with the applicable regulations governing minor transactions. *See* 49 U.S.C. 11321–26; 49 CFR part 1180. The Board is also accepting for consideration the three related filings, which are also in compliance with the applicable regulations. The Board reserves the right to require the filing of supplemental information as necessary to complete the record.

Public Inspection. The primary application and related filings are available for inspection in the library (Room 131) at the offices of the Surface Transportation Board, 395 E Street, SW., Washington, DC. In addition, the primary application and related filings may be obtained from Mr. Allen (representing Applicants) at the address indicated above.

Procedural Schedule. The Board has considered Applicants' request for an expedited procedural schedule filed on May 30, 2008, under which the Board would issue its final decision before the statutory deadline of 180 days after the filing of the primary application. The Board is adopting a procedural schedule that is similar to Applicants' proposed schedule, but providing more time for interested parties to file comments.

Under the procedural schedule adopted by the Board, comments on the Environmental Appendix are due to be filed by July 7, 2008. Any person who wishes to participate in this proceeding as a POR must file a notice of intent to participate no later than July 11, 2008; all comments, protests, requests for conditions, and any other evidence and argument in opposition to the primary application or related filings, including filings by DOJ and DOT, must be filed by August 11, 2008; and responses to comments, protests, requests for conditions, and other opposition and rebuttal in support of the primary application or related filings must be filed by September 5, 2008. As in past proceedings, DOJ and DOT will be allowed to file, on the response due date (here, September 5, 2008), their comments in response to the comments of other parties, and Applicants will be allowed to file (as quickly as possible thereafter) a response to any such comments filed by DOJ and/or DOT. Under this schedule, a public hearing or oral argument may be held on a date to be determined by the Board. The Board will issue its final decision by October 20, 2008, with an effective date of 15 days after its issuance, assuming that formal environmental review under NEPA is not required. For further information respecting dates, see the attached Appendix.

Notice of Intent To Participate. Any person who wishes to participate in this proceeding as a POR must file with the Board, no later than July 11, 2008, a notice of intent to participate, accompanied by a certificate of service indicating that the notice has been properly served on the Secretary of Transportation, the Attorney General of the United States, and Mr. Allen (representing Applicants).

If a request is made in the notice of intent to participate to have more than one name added to the service list as a POR representing a particular entity, the extra name will be added to the service list as a ''Non-Party.'' The list will reflect the Board's policy of allowing only one official representative per party to be placed on the service list, as specified in Press Release No. 97–68 dated August 18, 1997, announcing the implementation of the Board's ''One Party—One Representative'' policy for service lists. Any person designated as a Non-Party will receive copies of Board decisions, orders, and notices but not copies of official filings. Persons seeking to change their status must accompany that request with a written certification that he or she has complied with the service requirements set forth at 49 CFR 1180.4, and any other requirements set forth in this decision.

Service List Notice. The Board will serve, as soon after July 11, 2008, as practicable, a notice containing the official service list (the service-list notice). Each POR will be required to serve upon all other PORs, within 10 days of the service date of the service-list notice, copies of all filings previously submitted by that party (to the extent such filings have not previously been served upon such other parties). Each POR also will be required to file with the Board, within 10 days of the service date of the service-list notice, a certificate of service indicating that the service required by the preceding sentence has been accomplished. Every filing made by a POR after the service date of the service-list notice must have its own certificate of service indicating that all PORs on the service list have been served with a copy of the filing. Members of the United States Congress (MOCs) and Governors (GOVs) are not parties of record and need not be served with copies of filings, unless any Member or Governor has requested to be, and is designated as, a POR.

Comments, Protests, Requests for Conditions, and Other Opposition Evidence and Argument, Including Filings By DOJ and DOT. All comments, protests, requests for conditions, and any other evidence and argument in opposition to the primary application or related filings, including filings by DOJ and DOT, must be filed by August 11, 2008.

Because the Transaction proposed in the application is a minor transaction, no responsive applications will be permitted. *See* 49 CFR 1180.4(d)(1).

Protesting parties are advised that, if they seek either the denial of the application or the imposition of conditions upon any approval thereof, on the theory that approval (or approval without conditions) would harm competition and/or their ability to provide essential services, they must present substantial evidence in support of their positions. *See Lamoille Valley R.R. Co.* v. *ICC,* 711 F.2d 295 (DC Cir. 1983).

Responses To Comments, Protests, Requests for Conditions, and Other Opposition; Rebuttal In Support of the Primary Application Or Related Filings. Responses to comments, protests, requests for conditions, and other opposition submissions, and rebuttal in support of the primary application or related filings must be filed by September 5, 2008.

Public Hearing/Oral Argument. The Board may hold a public hearing or an oral argument in this proceeding on a date to be determined by the Board.

Discovery. Discovery may begin immediately. The parties are encouraged to resolve all discovery matters expeditiously and amicably.

Environmental Matters. Applicants assert in their application that the proposed Transaction would have insignificant environmental effects and therefore does not require a formal environmental review under the National Environmental Policy Act of 1969 (NEPA). Applicants state that the proposed Transaction would result in no significant changes in railroad operations that would exceed the thresholds triggering environmental review established in the Board's environmental rules at 49 CFR 1105.7(e)(4) or (5). No related rail construction or abandonment projects requiring Board approval have been proposed. Applicants further state that the Transaction is exempt under 49 CFR 1105.6(c)(2)(i) from environmental reporting requirements and exempt under 49 CFR 1105.8(b)(1) and (3) from historic preservation reporting requirements. Applicants also state that the proposed Transaction does not require preparation of a Safety Integration Plan pursuant to 49 CFR 1105.6.

To assist SEA in determining whether the Transaction would not have significant environmental impacts and would not require formal environmental review, SEA directed Applicants to prepare an Environmental Appendix providing additional details and explanation, including maps, supporting Applicants' conclusion that the Transaction does not warrant the preparation of formal environmental documentation. Applicants have prepared an Environmental Appendix and issued it for public review and comment to a wide range of appropriate Federal, state, and local agencies, government entities and other interested parties in the project area. The Environmental Appendix is available on the Board's Web site at *www.stb.dot.gov,* under ''E–LIBRARY/Filings'' (see Filings for June 6, 2008). Applicants also placed notices in major newspapers in potentially affected communities to announce the availability of the Environmental Appendix and the opportunity to file public comments.

Comments from all interested parties on the Environmental Appendix are to be postmarked by July 7, 2008. Based on its consideration of all timely comments on the Environmental Appendix and its own independent review of all available environmental information, SEA will recommend to the Board whether there is a need for formal environmental review in this case. The Board will then determine whether to issue a finding of no significant environmental impact, or, alternatively, whether an Environmental Assessment (EA) or Environmental Impact Statement (EIS) should be prepared. If an EA or EIS is required to meet the Board's NEPA obligations, the procedural schedule set forth here will be adjusted accordingly.

Comments On Environmental Appendix. All comments on the Environmental Appendix must be filed by July 7, 2008. Persons wishing to submit written comments on the Environmental Appendix should send: (1) one signed original to SEA by mail postmarked by July 7, 2008, to Office of the Secretary, Case Control Unit, STB Finance Docket No. 35147, Surface Transportation Board, 395 E Street, SW., Washington, DC 20423; [10] and (2) one copy to Applicants' attorney, Richard A. Allen. Comments can also be submitted electronically by following the instructions for ''e-filing'' at the Board's Web site at *www.stb.dot.gov.* Any questions or requests for additional information about the Board's environmental review process can be directed to Ken Blodgett of SEA, at 202–245–0305.

Filing/Service Requirements. Persons participating in this proceeding may file with the Board and serve on other parties: a notice of intent to participate (due by July 11, 2008); a certificate of service indicating service of prior pleadings on persons designated as PORs on the service-list notice (due by the 10th day after the service date of the service-list notice); any comments, protests, requests for conditions, and any other evidence and argument in opposition to the primary application or related filings (due by August 11, 2008); and any responses to comments, etc., and any rebuttal in support of the primary application or related filings (due by September 5, 2008).

[10] In their letter of transmittal, Applicants used the wrong zip code (20024, the zip code for the STB's building location), rather than 20423 (the Board's assigned zip code that follows the agency wherever it is located).

Filing Requirements. Any document filed in this proceeding must be filed either via the Board's e-filing format or in the traditional paper format as provided for in the Board's rules. Any person using e-filing should attach a document and otherwise comply with the instructions found on the Board's Web site at *www.stb.dot.gov* at the ''E–FILING'' link. Any person filing a document in the traditional paper format should send an original and 10 paper copies of the document (and also an electronic version) to: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

Service Requirements. One copy of each document filed in this proceeding must be sent to each of the following (any copy may be sent by e-mail only if service by e-mail is acceptable to the recipient): (1) Secretary of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590; (2) Attorney General of the United States, c/o Assistant Attorney General, Antitrust Division, Room 3109, Department of Justice, Washington, DC 20530; (3) Richard A. Allen (representing Applicants), Zuckert, Scoutt & Rasenberger, LLP, 888 Seventeenth Street, NW., Suite 700, Washington, DC 20006; and (4) any other person designated as a POR on the service-list notice.

Service of Decisions, Orders, and Notices. The Board will serve copies of its decisions, orders, and notices only on those persons who are designated on the official service list as either POR, MOC, GOV, or Non-Party. All other interested persons are encouraged to secure copies of decisions, orders, and notices via the Board's Web site at *www.stb.dot.gov* under ''E–LIBRARY/Decisions & Notices.''

Access To Filings. An interested person does not need to be on the service list to obtain a copy of the primary application or any other filing made in this proceeding. Under the Board's rules, any document filed with the Board (including applications, pleadings, etc.) shall be promptly furnished to interested persons on request, unless subject to a protective order. 49 CFR 1180.4(a)(3). The primary application and other filings in this proceeding will also be available on the Board's Web site at *www.stb.dot.gov* under ''E–LIBRARY/Filings.''

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

1. The primary application in STB Finance Docket No. 35147 and the related filings in STB Finance Docket

No. 35147 (Sub-Nos. 1 through 3) are accepted for consideration.

2. The parties to this proceeding must comply with the procedural schedule adopted by the Board in this proceeding as shown in the Appendix.

3. The parties to this proceeding must comply with the procedural requirements described in this decision.

4. This decision is effective on June 27, 2008.

Decided: June 23, 2008.

By the Board, Chairman Nottingham, Vice Chairman Mulvey, and Commissioner Buttrey. Vice Chairman Mulvey commented with a separate expression.

Anne K. Quinlan,

Acting Secretary.

Vice Chairman Mulvey, commenting:

While I vote today to accept for consideration this transaction as ''minor'' in accordance with the statutory definition of that type of transaction, I believe the time may have come to redefine what is ''minor'' and what is ''significant.'' This transaction involves several hundred miles of rail line in the New England region and affects a number of carriers. It is by no means ''minor'' as that term is commonly used.

APPENDIX—PROCEDURAL SCHEDULE [11]

May 30, 2008	Application, related notices of exemption, and motion to establish procedural schedule filed.
June 27, 2008	Notice of acceptance of application and notices of exemption to be published in **Federal Register**.
July 7, 2008	Comments on the Environmental Appendix due.
July 11, 2008	Notices of intent to participate in the proceeding due.
August 11, 2008	Comments, protests, requests for conditions, and supporting evidence, including filings for government agencies, due.
September 5, 2008	Responses to comments, protests, and requests for conditions, and rebuttal in support of Application due.
TBD	Public hearing or oral argument may be held.
October 20, 2008	Service of final decision.
November 4, 2008	Final decision effective.

[11] This schedule will be amended, if necessary, to accommodate formal environmental review, if needed.

This schedule would meet the procedural deadlines in 49 U.S.C. 11325(a) and (d).

[FR Doc. E8–14633 Filed 6–26–08; 8:45 AM]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 35149]

Mitchell-Rapid City Regional Railroad Authority—Modified Rail Certificate—Between Caputa and Rapid City, SD

On June 6, 2008, Mitchell-Rapid City Regional Railroad Authority (MRCRRA)[1] filed a notice for a modified certificate of public convenience and necessity under 49 CFR Part 1150, Subpart C, *Modified Certificate of Public Convenience and Necessity*, to operate a line of railroad between Caputa and Rapid City, SD (Caputa-Rapid City segment), owned by the South Dakota Department of Transportation (SDDOT). The Caputa-Rapid City segment extends from milepost 646.0, near Caputa, to milepost 659.6 in Rapid City, in Pennington County, SD, a distance of approximately 13.6 miles.

The Caputa-Rapid City segment is part of a larger line of railroad, extending from Mitchell, SD, to Rapid City, that was acquired by the State of South Dakota from the Chicago, Milwaukee, St. Paul & Pacific Railroad Company after the line was approved for abandonment.[2]

The State of South Dakota, through SDDOT, leased the Caputa-Rapid City segment to MRCRRA by agreement dated April 7, 2008. The line is currently out of service and requires rehabilitation before rail operations can commence. MRCRRA would provide service in its own name through a third-party contract operator, or by a sublease of the line to a third-party carrier.

The rail segment qualifies for a modified certificate of public convenience and necessity. *See Common Carrier Status of States, State Agencies and Instrumentalities and Political Subdivisions*, Finance Docket No. 28990F (ICC served July 16, 1981).

MRCRRA states that as of now no subsidy is involved and that there are no preconditions for shippers to meet in order to receive rail service.

This notice will be served on the Association of American Railroads (Car Service Division) as agent for all railroads subscribing to the car-service and car-hire agreement: Association of American Railroads, 50 F Street, NW., Washington, DC 20001; and on the American Short Line and Regional Railroad Association: American Short Line and Regional Railroad Association, 50 F Street, NW., Suite 7020, Washington, DC 20001.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: June 23, 2008.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–14631 Filed 6–26–08; 8:45 am]

BILLING CODE 4915–01–P

[1] MRCRRA is a political subdivision of the State of South Dakota.

[2] *See Richard B. Olgivie, Trustee of the Property of Chicago, Milwaukee, St. Paul & Pacific Railroad Company—Abandonment—In South Dakota, Iowa and Nebraska*, Docket No. AB–7 (Sub-No. 88) (ICC served May 14, 1980).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 730

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 730, Tax on Wagering.

DATES: Written comments should be received on or before August 26, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or

copies of the form and instructions should be directed to Allan Hopkins, at (202) 622–6665, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224 or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Tax on Wagering.

OMB Number: 1545–0235.

Form Number: Form 730.

Abstract: Form 730 is used to identify taxable wagers under Internal Revenue Code section 4401 and collect the tax monthly. The information is used to determine if persons accepting wagers are correctly reporting the amount of wagers and paying the required tax.

Current Actions: Form 730 has been reformatted to be scannable. New entry boxes have been added for a daytime telephone number, and to indicate a final return. Lines 4a and 4b each have a new entry to allow for the separate computation of tax amounts for wagers authorized under state law (line 4a) and for all other wagers (line 4b).

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profit organizations and individuals.

Estimated Number of Respondents: 102,164.

Estimated Time per Response: 8 hrs., 25 min.

Estimated Total Annual Burden Hours: 384,291.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 11, 2008.

Allan Hopkins,

IRS Reports Clearance Officer.

[FR Doc. E8–14557 Filed 6–26–08; 8:45 am]

BILLING CODE 4830–01–P

Corrections

Federal Register

Vol. 73, No. 125

Friday, June 27, 2008

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2007–0617; FRL–8570–2]

Clean Air Act Approval and Promulgation of Air Quality Implementation Plan Revision for North Dakota; Revisions to the Air Pollution Control Rules and Alternative Monitoring Plan for Mandan Refinery; Delegation of Authority for New Source Performance Standards

Correction

In rule document E8–11479 beginning on page 30308 in the issue of Tuesday, May 27, 2008 make the following correction:

§52.1820 [Corrected]

On page 30314, in the table at §52.1820(c) entitled State of North Dakota Regulations, in the first column, in the second entry, in the third line, ''m, 33–15–04–'' should read ''33–15–04–''.

[FR Doc. Z8–11479 Filed 6–26–08; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 9391]

RIN 1545-BF85

Source Rules Involving U.S. Possessions and Other Conforming Changes

Correction

In correction rule document C8–1105 appearing on page 32629 in the issue of Monday, June 9, 2008 make the following correction:

§1.937–2 [Corrected]

1. On page 19373, in §1.937–2(k) at *Example 2*.(ii), the equation is being reprinted correctly as set forth below.

$$\$100x\ \text{gain} \times \frac{945\ \text{days in possession holding period}}{1461\ \text{days in total holding period}}$$

[FR Doc. C8–1105 Filed 6–26–08; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,
June 27, 2008

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2008; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9046–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2008

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from January 2008 through March 2008, relating to the Medicare and Medicaid programs. This notice provides information on national coverage determinations (NCDs) affecting specific medical and health care services under Medicare. Additionally, this notice identifies certain devices with investigational device exemption (IDE) numbers approved by the Food and Drug Administration (FDA) that potentially may be covered under Medicare. This notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations and a list of Medicare-approved carotid stent facilities. Included in this notice is a list of the American College of Cardiology's National Cardiovascular Data registry sites, active CMS coverage-related guidance documents, and special one-time notices regarding national coverage provisions. Also included in this notice is a list of National Oncologic Positron Emissions Tomography Registry sites, a list of Medicare-approved ventricular assist device (destination therapy) facilities, a list of Medicare-approved lung volume reduction surgery facilities, a list of Medicare-approved clinical trials for fluorodeoxyglucose positron emissions tomography for dementia, and a list of Medicare-approved bariatric surgery facilities.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, and to foster more open and transparent collaboration efforts, we are also including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this 3-month time frame.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning these items. Copies are not available through the contact persons. (See Section III of this notice for how to obtain listed material.)

Questions concerning CMS manual instructions in Addendum III may be addressed to Ismael Torres, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services, C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–1864.

Questions concerning regulation documents published in the **Federal Register** in Addendum IV may be addressed to Gwendolyn Johnson, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services, C4–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–6954.

Questions concerning Medicare NCDs in Addendum V may be addressed to Patricia Brocato-Simons, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–0261.

Questions concerning FDA-approved Category B IDE numbers listed in Addendum VI may be addressed to John Manlove, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–13–04, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–6877.

Questions concerning approval numbers for collections of information in Addendum VII may be addressed to Melissa Musotto, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–6962.

Questions concerning Medicare-approved carotid stent facilities in Addendum VIII may be addressed to Sarah J. McClain, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–2994.

Questions concerning Medicare's recognition of the American College of Cardiology-National Cardiovascular Data Registry sites in Addendum IX may be addressed to JoAnna Baldwin, MS, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–7205.

Questions concerning Medicare's active coverage-related guidance documents in Addendum X may be addressed to Beverly Lofton, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–7136.

Questions concerning one-time notices regarding national coverage provisions in Addendum XI may be addressed to Beverly Lofton, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–7136.

Questions concerning National Oncologic Positron Emission Tomography Registry sites in Addendum XII may be addressed to Stuart Caplan, RN, MAS, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–8564.

Questions concerning Medicare-approved ventricular assist device (destination therapy) facilities in Addendum XIII may be addressed to JoAnna Baldwin, MS, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–7205.

Questions concerning Medicare-approved lung volume reduction surgery facilities listed in Addendum XIV may be addressed to JoAnna Baldwin, MS, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–7205.

Questions concerning Medicare-approved bariatric surgery facilities listed in Addendum XV may be addressed to Kate Tillman, RN, MA, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–9252.

Questions concerning fluorodeoxyglucose positron emission

tomography for dementia trials listed in Addendum XVI may be addressed to Stuart Caplan, RN, MAS, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–8564.

Questions concerning all other information may be addressed to Gwendolyn Johnson, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Centers for Medicare & Medicaid Services, C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–6954.

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs. These programs pay for health care and related services for 39 million Medicare beneficiaries and 35 million Medicaid recipients. Administration of the two programs involves (1) furnishing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public and (2) maintaining effective communications with regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act). We also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, and to foster more open and transparent collaboration, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the respective 3-month time frame.

II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of manual issuances, memoranda, substantive and interpretive regulations, NCDs, and FDA-approved IDEs published during the subject quarter to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) published in 1988, and the notice published March 31, 1993 (58 FR 16837). Those desiring information on the Medicare NCD Manual (NCDM, formerly the Medicare Coverage Issues Manual (CIM)) may wish to review the August 21, 1989, publication (54 FR 34555). Those interested in the revised process used in making NCDs under the Medicare program may review the September 26, 2003, publication (68 FR 55634).

To aid the reader, we have organized and divided this current listing into 11 addenda:

- Addendum I lists the publication dates of the most recent quarterly listings of program issuances.
- Addendum II identifies previous **Federal Register** documents that contain a description of all previously published CMS Medicare and Medicaid manuals and memoranda.
- Addendum III lists a unique CMS transmittal number for each instruction in our manuals or Program Memoranda and its subject matter. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manuals.
- Addendum IV lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the **Federal Register** during the quarter covered by this notice. For each item, we list the—
  - Date published;
  - **Federal Register** citation;
  - Parts of the Code of Federal Regulations (CFR) that have changed (if applicable);
  - Agency file code number; and
  - Title of the regulation.
- Addendum V includes completed NCDs, or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCDM in which the decision appears, the title, the date the publication was issued, and the effective date of the decision.
- Addendum VI includes listings of the FDA-approved IDE categorizations, using the IDE numbers the FDA assigns. The listings are organized according to the categories to which the device numbers are assigned (that is, Category A or Category B), and identified by the IDE number.
- Addendum VII includes listings of all approval numbers from the Office of Management and Budget (OMB) for collections of information in CMS regulations in title 42; title 45, subchapter C; and title 20 of the CFR.
- Addendum VIII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients.
- Addendum IX includes a list of the American College of Cardiology's National Cardiovascular Data registry sites. We cover implantable cardioverter defibrillators (ICDs) for certain indications, as long as information about the procedures is reported to a central registry.
- Addendum X includes a list of active CMS guidance documents. As required by section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003), we will begin listing the current versions of our guidance documents in each quarterly listings notice.
- Addendum XI includes a list of special one-time notices regarding national coverage provisions. We are publishing a list of issues that require public notification, such as a particular clinical trial or research study that qualifies for Medicare coverage.
- Addendum XII includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.
- Addendum XIII includes a listing of Medicare-approved facitilites that receive coverage for ventricular assist devices used as destination therapy. All facilities were required to meet our standards in order to receive coverage for ventricular assist devices implanted as destination therapy.
- Addendum XIV includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial are also eligible to receive coverage.
- Addendum XV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities

must meet our standards in order to receive coverage for bariatric surgery procedures.

• Addendum XVI includes a listing of Medicare-approved clinical trials for fluorodeoxyglucose positron emission tomography (FDG–PET) for dementia and neurodegenerative diseases.

III. How To Obtain Listed Material

A. Manuals

Those wishing to subscribe to program manuals should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses: Superintendent of Documents, Government Printing Office, ATTN: New Orders, P.O. Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 512–1800, Fax number (202) 512–2250 (for credit card orders); or National Technical Information Service, Department of Commerce,5825 Port Royal Road, Springfield, VA 22161,Telephone (703) 487–4630.

In addition, individual manual transmittals and Program Memoranda listed in this notice can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell. Additionally, most manuals are available at the following Internet address: *http://cms.hhs.gov/manuals/default.asp.*

B. Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. Interested individuals may purchase individual copies or subscribe to the **Federal Register** by contacting the GPO at the address given above. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is also available on 24x microfiche and as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is *http://www.gpoaccess.gov/fr/index.html,* by using local WAIS client software, or by telnet to swais.gpoaccess.gov, then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

C. Rulings

We publish rulings on an infrequent basis. CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters. Interested individuals can obtain copies from the nearest CMS Regional Office or review them at the nearest regional depository library. We have, on occasion, published rulings in the **Federal Register**. Rulings, beginning with those released in 1995, are available online, through the CMS Home Page. The Internet address is *http://cms.hhs.gov/rulings.*

D. CMS' Compact Disk-Read Only Memory (CD-ROM)

Our laws, regulations, and manuals are also available on CD-ROM and may be purchased from GPO or NTIS on a subscription or single copy basis. The Superintendent of Documents list ID is HCLRM, and the stock number is 717–139–00000–3. The following material is on the CD–ROM disk:

• Titles XI, XVIII, and XIX of the Act.

• CMS-related regulations.

• CMS manuals and monthly revisions.

• CMS program memoranda.

The titles of the Compilation of the Social Security Laws are current as of January 1, 2005. (Updated titles of the Social Security Laws are available on the Internet at *http://www.ssa.gov/OP_Home/ssact/comp-toc.htm.*) The remaining portions of CD–ROM are updated on a monthly basis.

Because of complaints about the unreadability of the Appendices (Interpretive Guidelines) in the State Operations Manual (SOM), as of March 1995, we deleted these appendices from CD–ROM. We intend to re-visit this issue in the near future and, with the aid of newer technology, we may again be able to include the appendices on CD–ROM.

Any cost report forms incorporated in the manuals are included on the CD–ROM disk as LOTUS files. LOTUS software is needed to view the reports once the files have been copied to a personal computer disk.

IV. How To Review Listed Material

Transmittals or Program Memoranda can be reviewed at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL.

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most Federal Government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library.

For each CMS publication listed in Addendum III, CMS publication and transmittal numbers are shown. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare Benefit Policy publication titled ''Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions,'' use CMS–Pub. 100–03, Transmittal No. 80.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: June 4, 2008.

Jacquelyn Y. White,

Director, Office of Strategic Operations and Regulatory Affairs.

Addendum I

This addendum lists the publication dates of the most recent quarterly listings of program issuances.

March 24, 2006 (71 FR 14903)
June 23, 2006 (71 FR 36101)
September 29, 2006 (71 FR 57604)
December 22, 2006 (71 FR 77202)
March 30, 2007 (72 FR 15282)
June 22, 2007 (72 FR 34508)
September 28, 2007 (72 FR 55282)
December 28, 2007 (72 FR 73990)
April 1, 2008 (73 FR 17422)

Addendum II—Description of Manuals, Memoranda, and CMS Rulings

An extensive descriptive listing of Medicare manuals and memoranda was published on June 9, 1988, at 53 FR 21730 and supplemented on September 22, 1988, at 53 FR 36891 and December 16, 1988, at 53 FR 50577. Also, a

complete description of the former CIM (now the NCDM) was published on August 21, 1989, at 54 FR 34555. A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 16, 1992, at 57 FR 47468.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 2008

Transmittal No.	Manual/Subject/Publication No.
	Medicare General Information (CMS-Pub. 100–01)
00	None.
	Medicare Benefit Policy (CMS-Pub. 100–02)
80	Requirements for Ordering and Following Orders for Diagnostic Tests Clinical Laboratory Services; Requirements for Ordering and Following Orders for Diagnostic Tests Definitions; Interpreting Physician Determines a Different Diagnostic Test is Appropriate; Rules for Testing Facility to Furnish Additional Tests; Rules for Testing Facility Interpreting Physician to Furnish Different or Additional Tests; Surgical/Cytopathology Exception.
81	Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen.
82	January 2008 Update of the Hospital Outpatient Prospective Payment System; Manualization; Outpatient Hospital Services; Limitations on Coverage of Certain Services Furnished to Hospital Outpatients; General Rule; Exception to Limitation; Outpatient Defined; Encounter Defined; Diagnostic Services Defined; Coverage of Outpatient Diagnostic Services; Outpatient Diagnostic Services Under Arrangements; Diagnostic Services Defined; Coverage of Outpatient Diagnostic Services; Outpatient Diagnostic Services Under Arrangements; Outpatient Therapeutic Services; Diagnostic Service Defined; Coverage of Outpatient Diagnostic Services; Outpatient Diagnostic Services Under Arrangements; Outpatient Therapeutic Services; Coverage of Outpatient Therapeutic Services Incident to a Physicians Service; Furnished on or After August 1, 2000; Outpatient Observation Services; Laboratory Services Furnished to Nonhospital Patients by Hospital Laboratory.
83	Clinical Lab: New Automated Test for the AMCC Panel Payment Algorithm Automated Multi-Channel Chemistry Tests.
84	Update to Audiology Policies; Audiological Diagnostic Testing; Definition of Qualified Audiologist.
85	Psychological and Neuropsychological Tests.
	Medicare National Coverage Determination (CMS-Pub. 100–03)
80	Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions.
	Medicare Claims Processing (CMS-Pub. 100–04)
1405	SUBJECT: Reprocessing of Certain Hospital Inpatient Prospective Payment System Claims.
1406	January 2008 Quarterly Average Sales Price Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files.
1407	Outpatient Therapy Caps Without KX Modifier Exceptions Start January 1, 2008 The Financial Limitation.
1408	Modification to the Model Medicare Redetermination Notice (for Partly or Fully Unfavorable Redeterminations); Medicare Redetermination Notice (for Partly or Fully Unfavorable Redeterminations).
1409	Correction to Pub. 100–04, Chapter 17, Section 100.2.1; CAP Required Modifiers.
1410	Annual Type of Service Update.
1411	April 2008 Update to the Medicare Code Editor and Group.
1412	Reporting of Hematocrit or Hemoglobin Levels on All Claims for the Administration of Erythropoiesis Stimulating Agents Implementation of New Modifiers for Non-ESRD Indications, and Reporting of Hematocrit/Hemoglobin Levels on all Non-ESRD, Non-ESA Claims Requesting Payment for Anti-Anemia Drugs; Epoetin Alfa (EPO) Provided in the Hospital Outpatient Department; Payment for Aranesp in the Hospital Outpatient Department; Reporting of Hematocrit and/or Hemoglobin Levels; Required Modifiers for ESAs As Administered to Non-ESRD Patients; Hospitals Billing for EPO and Darbepoetin Alfa (Aranesp) for Non-ESRD Patients; The Competitive Acquisition Program for Drugs and Biologicals Not Paid on a Cost or Prospective Payments Basis; Claims Processing Instructions for CAP Claims for the Local Carriers; Items 14–33 Provider of Service or Supplier Information.
1413	Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions; Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy.
1414	Outpatient Therapy Caps without KX Modifier Exceptions Start January 1, 2008 The Financial Limitation.
1415	Additional Payable ''C'' Drug Codes for January 1, 2008 in ASCs.
1416	Clarification of Bone Mass Measurement Billing Requirements; Bone Mass Measurements; Payment Methodology and Healthcare Common Procedure Coding Systems (HCPCS) Coding.
1417	January 2008 Update of the Hospital Outpatient Prospective Payment System.
1418	New Healthcare Common Procedure Coding System Modifiers when Billing for Patient Care in Clinical Research Studies; Carrier Specific Requirements for Certain Specialties/Services; Billing Requirements for Providers Billing Routine Costs of Clinical Trials; Involving a Category A Investigation Device Exemptions; Billing Requirements for Providers Billing Routine Costs of Clinical Trials; Involving a Category B Investigation Device Exemptions; Billing Requirements for Clinical Trials; Reserved for Future Use.
1419	January 2008 Integrated Outpatient Code Specifications Version 9.0.
1420	Clarification Regarding the Coordination of Benefits Agreement; Medigap Claim-Based Crossover Process; Supplemental Coverage/Medigap; COB Training Partner and Medigap Plan Crossover Claim Requirements; Patient and Insured Information; MSN Messages; Coordination of Benefits Agreement Medigap Claim-Based Crossover Process.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 2008—Continued

Transmittal No.	Manual/Subject/Publication No.
1421	Update of Institutional Claims References; Billing Form as Request for Payment; Beneficiary Request for Payment on Provider Record—UB–92 and Electronic Billing (Part A and Part B); When an Inpatient Admission May Be Changed to Outpatient Status; Noncovered Charges on Outpatient Bills; Line-Item Modifiers Related to Reporting of Noncovered Charges When Covered and Noncovered Services Are on the Same Institutional Claim; Form Prescribed by CMS In Accordance with CMS Instructions; Handling Incomplete or Invalid Submissions; Payment Floor Standards; Data Element Requirements Matrix; Claim Change Reason Codes; Inpatient Part A Hospital Adjustment Bills; (previously 130.3.1.2)—Tolerance Guides for Submitting SNF Inpatient Adjustment Request; (previously 130.3.3)—SNF Inpatient Claim Adjustment Instructions; (previously 130.3.4)—Patient Does Not Return From SNF Leave of Absence, and Last Bill Reported Patient Status as Still Patient (30); Billing and Claims Processing Requirements Related to HINNs; Billing and Claims Processing Requirements Related to Expedited Determinations; Source of Admission—Outpatient Hospital; Forms; DRG Grouper Program; Payment to Hospitals and Units Excluded from IPPS for Direct Graduate; Medical Education and Nursing and Allied Health (NandAH); Education for Medicare Advantage Enrollees; Adjustment Bills; Billing Requirements Under IRF PPS; Shared Systems and CWF Edits; System Edits; Benefits Exhausted; Completion of the Uniform (Institutional Provider) Bill (Form CMS–1450); Notice of Election for RNHCI; Required Data Elements on Claims for RNHCI Services; IPF PPS System Edits; Where to Report Modifiers on the UB–92 (Form CMS–1450) and ANSI X12N Formats; Optional Method for Outpatient Services: Cost-Based Facility Services Plus 115; Percent Fee Schedule Payment for Professional Services; Bill Review for Partial Hospitalization Services Provided in Community Mental Health Centers; Line Item Date of Service Reporting for Partial Hospitalization; Line Item Date of Service Reporting on Form CMS–1450; Off-Site CORF Services; Notifying Patient of Service Denial; Billing Skilled Nursing Facility PPS Service; Input/Output Record Layout; Leave of Absence; Services in Excess of Covered Services; Billing Formats; Billing; Calculation of Case Mix Adjusted Composite Rate; In-Facility Dialysis Bill Processing Procedures; Required Information for In-Facility Claims Paid Under the Composite Rate; EPO Facility Billing Requirements; Aranesp Facility Billing Requirements; General Intermediary Bill Processing Procedures for Method I Home Dialysis Services; Required Billing Information for Method I Claims; Billable Revenue Codes Under Method II; Unbillable Revenue Codes Under Method II; General Billing Requirements; General Guidelines for Processing Home Health Agency Claims; Special Billing Situations Involving OASIS Assessment; Heathcare Common Procedure Coding System Coding Requirements; Payment Methodology and HCPCS Coding; General Billing Guidelines—Intermediaries and Carriers; Intermediary Guidelines; Hospital Billing Under Part B; Billing and Payment Instructions for Fiscal Intermediaries (FIs); Requirements for Billing FIs for Immunosuppressive Drugs; Claims Submitted to FIs for Mass Immunizations of Influenza and Pneumococcal Pneumonia Vaccine; Healthcare Common Procedure Coding System and Diagnosis Codes for Mammography Services Diagnoses Codes; HHA Recertification for Home Oxygen Therapy; Billing/Claim Formats; ICD–9–CM Diagnosis and Procedure Codes; Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities; Billing Requirements for Providers Billing Category B IDEs.
1423	Summary of Policies in the 2008 Medicare Physician Fee Schedule and the Telehealth Originating Site Facility Fee Payment Amount.
1424	Correction to Low Utilization Payment Adjustment Add-on Payments Under the Refined Home Health Prospective Payment System; Composition of Health Insurance Prospect Payment System Codes for Home Health Prospective Payment System; Request for Anticipated Payment; Home Health Prospective Payment System Claims; Input/Output Record Layout; Decision Logic Used by the Pricer on RAPs; Decision Logic Used by the Pricer on Claims; Special Billing Situations Involving OASIS Assessments; Temporary Suspension of Home Health Services.
1425	Medicare Part A Skilled Nursing Facility Prospective Payment System Pricer; Update FY 2008 for 2 Core-Based Statistical Areas with New Wage Index; Values—Correction.
1426	Announcement of Medicare Rural Health Clinics and Federally Qualified Health Centers Payment Rate Increases; Payment Rate for Independent and Provider Based Rural Health Clinics and Federally Qualified Health Clinics.
1427	New Value Code to Report Patient Prior Payments.
1428	Issued to a specific audience, not posted Internet/Intranet due to Confidentiality of Instruction.
1429	Modification of Payment Window Edits in the Common Working File to Look at Line Item Dates of Service on Outpatient Claims; Outpatient Services Treated as Inpatient Services.
1430	Use of HCPCS V2787 When Billing Approved Astigmatism-Correcting; Intraocular Lens in Ambulatory Surgery Centers Physician Offices, and Hospital Outpatient Departments; Payment for Services and Supplies; Coding and General Billing Requirements.
1431	Update to the Implementation Date for Home Health Agencies Providing Durable Medical Equipment in Competitive Bidding Areas; General Guidelines for Processing Home Health Agency Claims; Home Health Prospective Payment System Consolidated Billing.
1432	Medicare Fee-for-Service Legacy Provider IDs Prohibited on Form CMS–1500 and Form CMS–1450 (UB–04) Claims; Carrier Data Element Requirements; Item 14–3 Provider of Service or Supplier Information.
1433	Smoking and Tobacco Use Cessation Counseling BILLING CODE Update; Health Common Procedure Coding System and Diagnosis Coding; Carrier Billing Requirements; FI Billing Requirements.
1434	Extension of the Dates of Service Eligible for the Physician Scarcity Area; Bonus Payment; Billing and Payment in a Physician Scarcity Area; ZIP Code Files; Billing and Payment in a Physician Scarcity Area; Identifying Physician Scarcity Area Locations.
1435	Emergency Update to the 2008 Medicare Physician Fee Schedule Database.
1436	Modifications to the National Coordination of Benefits Agreement; Crossover Process; Consolidated Claims Crossover Process; Consolidation of the Claims Crossover Process; Coordination of Benefits Agreement; Detailed Error Report Notification Process.
1437	Change in the Amount in Controversy Requirement for Administrative Law; Judge Hearings and Federal District Court Appeals; Right to an ALJ Hearing; Requests for U.S. District Court Review by a Party.
1438	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
1439	Removal of Outdated References to Christian Science Sanatoria from Medicare Systems.
1440	Medicare, Medicaid, and State Children's Health Insurance Program Extension Act of 2007 Changes to Independent Laboratory Billing for the Technical Component of Physician Pathology Services; Technical Component of Physician Pathology; Hospital Patients.
1441	New "K" Code for Replacement Interface Material.
1442	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 2008—Continued

Transmittal No.	Manual/Subject/Publication No.
1443	Home Health Prospective Payment System Refinement and Rate; Update for Calendar Year 2008; Basis of Medicare Prospective Payment Systems and Case-Mix.
1444	Modification to Existing Medicare Summary Notice Procedures; Regarding the MSN Customer Service Information Box, Beneficiary Estate Information and the Appeals Address; Title Section of the MSN Appeals Section; Title Section.
1445	January 2008 Update of the Hospital Outpatient Prospective Payment System; Manualization; Payment Status Indicators; APC Payment Groups; Composite APCs; Calculation of APC Payment Rates; Packaging; Combinations of Packaged Services of Different Types That Are Furnished on the Same Date of Service; Discounting; Payment Adjustments; Outlier Adjustments; Calculation of Overall Cost to Charge Ratios for Hospitals; Paid Under the Outpatient Prospective Payment System and Community Mental Health Centers Paid Under the Hospital; Requirement to Calculate CCRs for Hospitals Paid Under OPPS and for CMHC Circumstances in Which CCRs Are Used; Selection of the CCR To Be Used; Mergers, Acquisitions, and Other Ownership Changes; New Providers and Providers with Cost Report Periods Less Than a Full Year; Substitution of Statewide CCRs for Extreme OPPS Hospital Specific CCRs; Methodology for Calculation of Hospital Overall CCR for Hospitals That Do Not Have Nursing and Paramedical Education Programs; Methodology for Calculation of Hospital Overall CCR for Hospitals That Have Nursing and Paramedical Education Programs; Methodology for Calculation of CCR for CMHCs; Location of Statewide CCRs, Tolerances for Use of Statewide CCRs in Lieu of Calculated CCRs, and Cost Centers To Be Used in the Calculation of CCRs; Reporting of CCRs for Hospitals Paid Under OPPS and for CMHCs; Packaged Revenue Codes; Revenue Codes for ''Sometimes Therapy'' Services; Use of Modifiers for Discontinued Services; OPPS Coinsurance; Outpatient Pricer; Outpatient Provider Specific File; Changes to the OPPS Pricer Logic Effective January 1, 2003; Billing for Devices Under the OPPS; Billing and Payment for Brachytherapy Sources; Billing for Brachytherapy Sources—General; Definition of Brachytherapy Source for Separate Payment; Billing of Brachytherapy Sources Ordered for a Specific Patient; Billing for Brachytherapy Source Supervision, Handling, and Loading Costs; Transitional Outpatient Payments for CY 2006–CY 2008; Clinic and Emergency Visits; Critical Care Services; Special Services for OPPS Billing; Billing for Corneal Tissue; Hospital Services For Patients with End-Stage Renal Disease; Billing Codes for Intensity Modulated Radiation Therapy and Stereotactic; Billing for IMRT Planning and Delivery; Additional Billing Instructions for IMRT Planning; Billing for Multi-Source Photon (Cobalt 60-Based) Stereotactic Radiosurgery; Planning and Delivery; Billing for Linear Accelerator (Robotic Image-Guided and Non-Robotic Image-Guided) SRS Planning and Delivery; Billing for Amniotic Membrane; Billing and Payment for Cardiac Rehabilitation Services; Billing and Payment for Alcohol and/or Substance Abuse Assessment and Intervention Services; Billing for Cardiac Echocardiography Services; Cardiac Echocardiography Without Contrast; Cardiac Echocardiography With Contrast; Billing for Nuclear Medicine Procedures; Coding and Payment for Drugs, Biologicals, and Radiopharmaceuticals; Coding and Payment for Drug Administration; Observation Services Overview; Reporting Hours of Observation; Billing and Payment for Observation Services Furnished Between January 1, 2006 and December 31, 2007; Billing and Payment for All Hospital Observation Services Furnished Between January 1, 2006 and December 31, 2007; Separate and Packaged Payment for Direct Admission to Observation Between January 1, 2006 and December 31, 2007; Separate and Packaged Payment for Observation Services Furnished Between January 1, 2006 and December 31, 2007; Billing and Payment for Observation Services Furnished on or After January 1, 2008; Billing and Payment for Observation Services Beginning January 1, 2008; Billing and Payment for Direct Admission to Observation Care Beginning January 1, 2008; Services Not Covered as Observation Services; Hospital Billing Under Part B; Payment Rules for Drugs and Biologicals; Drugs, Biologicals, and Radiopharmaceuticals.
1446	Update to Common Working File (CWF Edits) 7284 and 7548; Indian Health Service/Tribal Hospital Inpatient Social Admits; FI—Social Admissions.
1447	Reporting of Additional Data To Describe Services on Hospice Claims; Levels of Care; Data Required on Claim to FI.
1448	Adjudicating Claims for Immunosuppressive Drugs When Medicare Did Not Pay for the Original Transplant; Billing for Immunosuppressive Drugs.
1450	Update to the Common Working File to Allow the Posting of Skilled Nursing Facility and Swing Bed Claims to the Beneficiary's Spell of Illness When Qualifying Stay Criteria Are Not Met; Billing When Qualifying Stay or Transfer Criteria Are Not Met.
1451	Clinical Lab: New Automated Test for the AMCC Panel Payment Algorithm; Organ or Disease Oriented Panel.
1452	Instructions for Downloading the Medicare ZIP Code File for July 2008.
1453	Systems Changes for Prescription Order Numbers for the Competitive Acquisition Program for Part B Drugs and Biologicals; Submitting the Prescription Order Numbers and No Pay Modifiers; Further Editing on the Prescription Order Number; Carrier Specific Requirements for Certain Specialties/Services.
1454	Department of Veterans Affairs Claims Adjudication Services Project—New IOM Chapter—Pub. 100–04, Chapter 37 ''Department of Veterans Affairs Claims Adjudication Services Project''; Background on the Veterans Affairs Claims Adjudication Services Project; Requirements for Processing Veterans Affairs Claims; Department of Veterans Affairs Claims Adjudication: Coinsurance and Deductible; Generating Unsolicited Responses to the Veterans Affairs; Use of Legacy Provider Numbers After National Provider Identifiers Are Fully Implemented.
1455	Part B Drug Competitive Acquisition Program Quarterly Drug List Update.
1456	Manualization of Payment for Outpatient End-Stage Renal Disease-Related Services; Monthly Capitation Payment Method for Physicians' Services Furnished to Patients on Maintenance Dialysis; Payment for End-Stage Renal Disease-Related Services Under the Monthly Capitation Payment; (Center-Based Patients); Payment for Managing Patients on Home Dialysis; Patients Who Switch Modalities (Center to Home and Vice Versa); Payment for End-Stage Renal Disease-Related Services (Per Diem); Guidelines for Physician or Practitioner Billing (Per Diem); Data Required on Claim for Monthly Capitation Payment; Controlling Claims Paid Under the Monthly Capitation Payment Method.
1457	Redeterminations of Overpayments; The Redetermination.
1458	Teaching Physician Requirements for End-Stage Renal Disease Monthly; Capitation Payment; Miscellaneous.
1459	Comprehensive Outpatient Rehabilitation Facility Billing Requirement; Updates for Fiscal Year 2008; Allowable Revenue Codes on Comprehensive Outpatient Rehabilitation Facility; 75x Bill Types; Proper Reporting of Nursing Services by CORFS—FIs; Payment of Drugs, Biologicals, and Supplies in a Comprehensive Outpatient Rehabilitation Facility; Billing for Social Work and Psychological Services in a Comprehensive Outpatient Rehabilitation Facility; Billing for Respiratory Therapy Services in a Comprehensive Outpatient Rehabilitation Facility; FI Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B; Virus Vaccines and Their Administration.
1460	Subsequent Hospital Visits and Hospital Discharge Day Management Services (Codes 99231—99239).

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 2008—Continued

Transmittal No.	Manual/Subject/Publication No.
1461	Clarification to CR 5744—Payment Allowance Update for the Influenza Virus Vaccine CPT 90660 and Further Instruction Regarding the Pneumococcal Vaccine CPT 90669; Healthcare Common Procedure Coding System and Diagnosis Codes.
1462	Healthcare Provider Taxonomy Codes Update April 2008.
1463	ZIP Code Files by Date of Service; Claims Processing Instructions for Payment Jurisdiction for Claims Received on or after April 1, 2004; Transition Overview.
1464	Quarterly Update to Correct Coding Initiative (CCI) Edits, Version 14.1, Effective April 1, 2008.
1465	Payment for Initial Hospital Care Services (Codes 99221–99233) and Observation or Inpatient Care Services (Including Admission and Discharge Services) (Codes 99234–99236).
1466	Payment for Hospital Observation Services (Codes 99217–99220) and Observation or Inpatient Care Services (Including Admission and Discharge Services—Codes 99234–99236).
1467	Modification to Existing Medicare Summary Notice Procedures Regarding the Customer Service Information Box; Title Section of the Medicare Summary Notice; Appeals Section.
1468	Claim Status Category Code and Claim Status Code Update.
1469	Document Control Number Search Feature.
1470	Update to Audiology Policies; Audiological Diagnostic Tests, Speech-Language Evaluations and Treatments.
1471	Healthcare Common Procedure Coding System Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments Edits.
1472	Update of Institutional Claims References; Billing Form as Request for Payment; Beneficiary Request for Payment on Provider Record—UB–04 and Electronic Billing (Part A and Part B); When an Inpatient Admission May Be Changed to Outpatient Status; Noncovered Charges on Outpatient Bills; Line-Item Modifiers Related to Reporting of Noncovered Charges; When Covered and Noncovered Services Are on the Same Institutional Claim Form Prescribed by CMS In Accordance with CMS Instructions; Handling Incomplete or Invalid Submissions; Payment Floor Standards; Data Element Requirements Matrix; Claim Change Reason Codes; Inpatient Part A Hospital Adjustment Bills; Tolerance Guides for Submitting SNF Inpatient Adjustment Requests; SNF Inpatient Claim Adjustment Instructions; Patient Does Not Return From SNF Leave of Absence, and Last Bill Reported; Patient Status as Still Patient (30); Billing and Claims Processing Requirements Related to HINNs; Billing and Claims Processing Requirements Related to Expedited Determinations; Data Element Requirements Matrix (FI); Source of Admission—Outpatient Hospital; Forms; DRG GROUPER Program; Payment to Hospitals and Units Excluded from IPPS for Direct Graduate Medical Education and Nursing and Allied Health (NandAH) Education for Medicare AdvantageEnrollees; Adjustment Bills; Billing Requirements Under IRF PPS; Shared System and CWF Edits; System Edits; Benefits Exhausted; Completion of the Uniform (Institutional Provider) Bill (Form CMS–1450) Notice of Election for RNHCI; Required Data Elements on Claims for RNHCI Services; IPF PPS System Edits; Where to Report Modifiers on the UB–92 (Form CMS–1450) and ANSI X12N Formats; Bill Review for Partial Hospitalization; Services Provided in Community Mental Health Centers; Line Item Date of Service Reporting for Partial Hospitalization; Line Item Date of Service Reporting on Form CMS–1450; Off-Site CORF Services; Notifying Patient of Service Denial; Billing SNF PPS Services; Input/Output Record Layout; Leave of Absence; Services in Excess of Covered Services; Billing Formats; Billing; Calculation of Case Mix Adjusted Composite Rate; Facility Dialysis Bill Processing Procedures; Required Information for In-Facility Claims Paid Under the Composite Rate; Epoetin Alfa (EPO) Facility Billing Requirements; Darbepoetin Alfa (Aranesp) Facility Billing Requirements; General Intermediary Bill Processing Procedures for Method I Home Dialysis Services; Required Billing Information for Method I Claims; Billable Revenue Codes Under Method II; Unbillable Revenue Codes Under Method II; General Billing Requirements; Special Billing Situations Involving OASIS Assessments; Healthcare Common Procedure Coding System Coding Requirements; Payment Methodology and Healthcare Common Procedure Coding System Coding; General Billing Guidelines—Intermediaries and Carriers; Intermediary Guidelines; Hospital Billing Under Part B; Billing and Payment Instructions for FIs; Requirements for Billing FI for Immunosuppressive Drugs; Claims Submitted to FIs for Mass Immunizations of Influenza and PPV; HCPCS and Diagnosis Codes for Mammography Services; Diagnoses Codes; HHA Recertification for Home Oxygen Therapy; Billing/Claim Formats; ICD–9–CM Diagnosis and Procedure Codes; Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities; Billing Requirements for Providers Billing Category B IDEs.
1473	Payment for Inpatient Hospital Visits—General (Codes 99221–99239).
1474	Changes to the Long Term Care Hospital Prospective Payment System (LTCH PPS) Pricer Based on the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Recurring CR: R20812Q).
1475	Remittance Advice Remark Code and Claim Adjustment Reason Code Update.
1476	Correction to Low Utilization Payment Adjustment Add-On Payments Under the Refined Home Health Prospective Payment System; Composition of Home Health Prospective Payment System Codes for Home; Health Prospective Payment System; Request for Anticipated Payment; Home Health Prospective Payment System Claims; Input/Output Record Layout; Decision Logic Used by the Pricer on RAPs; Decision Logic Used by the Pricer on Claims; Special Billing Situations Involving OASIS Assessments; Temporary Suspension of Home Health Services.
1477	New Waived Tests.
1478	Additional Clarification to Chapter 17, Section 40, Regarding Processing of Drug Claims with the JW Modifier; Discarded Drugs and Biologicals.
1479	April 2008 Inpatient Rehabilitation Facility Prospective Payment System; Pricer Changes; Income Patients; Low-Income Patient Adjustment: The Supplemental Security Income; Medicare Beneficiary Data for Inpatient Rehabilitation Facilities Paid Under the Prospective Payment System.
1480	Web site for Additions and Deletions of ZIP Codes Requiring a Plus Four ZIP Code Extension.
1481	Type of Service Corrections; Type of Service.
1482	April Update to the 2008 Medicare Physician Fee Schedule Database.
1483	April 2008 Integrated Outpatient Code Editor Specifications Version 9.1.
1484	April 2008 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 2008—Continued

Transmittal No.	Manual/Subject/Publication No.
	Medicare Secondary Payer (CMS-Pub. 100–05)
58	Insertion of the Debt Collection System User Guide into the Medicare Secondary Payer Section of the Manual and Associated Revisions/Updates to the Debt Collection System User Guide; 1–DCS.
59	Treasury Collections on Medicare Secondary Payor Debt; Treasury Collections; Background; Intra-Governmental Payment and Collection System; Debt Collection System; Collection/Refund Spreadsheet; Financial Reporting for Collection/Refund Spreadsheet; Debt Paid in Full; Treasury Approved Extended Repayment Schedule; Excess Collections; Applying an Excess Collection; If the Debtor Has Other Outstanding Debt; If the Debtor Has No Other Outstanding Debt; Additonal Instructions for MSP Excess Collection.
	Medicare Financial Management (CMS-Pub. 100–06)
134	Recurring Update Notification for the Notice of New Interest Rate for Medicare Overpayments and Underpayments—2nd Notification for FY 2008.
135	Clarification Regarding the Coordination of Benefits Agreement Medigap; Claim-Based Crossover Process; Coordination of Medicare and Complementary Insurance Programs.
136	Revisions to Debt Referral Instructions; Treasury Offset Program; Debt Ineligible for Referral; Intent to Refer Letter; Response to Intent to Refer Letter; Debt Collection System; Cross Servicing Collection Efforts; Actions Subsequent to DCS Input; Transmission of Debt; Update to DCS After Transmission; Collections; Background; Intra-governmental Payment and Collection System; Collections Posted to the Debt Collection System; Collection/Refund Spreadsheet; Debt Paid in Full; Extended Repayment Schedule; Excess Collections; Applying Excess Collections; If the Debtor Has Other Outstanding Debt; If the Debtor Has No Other Outstanding Debt; Financial Reporting for Non-MSP Debt; Financial Reporting for Collections Received on Debts From Cross Servicing; Intermediary Claims Accounts Receivable.
137	Reporting Costs Directly Associated with the Reimbursement Advisory Committee Program; Reporting Administrative Costs Directly Associated with the Reimbursement; Advisory Committee Program.
	Medicare State Operations Manual (CMS-Pub. 100–07)
31	Revision of Appendix P—Survey Protocol for Long Term Care Facilities.
32	Revisions to Chapter 2, ''Critical Access Hospitals and Appendix W, Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals and Swing-Beds in Critical Access Hospitals''; Verification Criteria; Relocation of Critical Access Hospitals With A Grandfathered Necessary Provider Designation.
33	Update to Chapter 2, ''The Certification Process,'' Sections 2021 and 2022.
	Medicare Program Integrity (CMS-Pub. 100–08)
231	NPI Number for Medical Review; Data Analysis.
232	Clarification of Standards for Processing CMS–855 Enrollment Applications; CMS–855 Medicare Enrollment Applications; Timeliness and Accuracy Standards; Standards for Initial Applications; Paper Applications—Timeliness; Paper Applications—Accuracy; Web-Based Applications—Timeliness; Web-Based Applications—Accuracy; Standards for Changes of Information; Paper Applications—Timeliness; Paper Applications—Accuracy; Web-Based Applications—Timeliness; Web-Based Applications—Accuracy.
233	Update to Chapter 10; Special Verification Procedures for CMS–855A Applications; Jurisdictional Issues; Changes of Ownership; Definitions; Determining Whether a Change of Ownership (CHOW) Has Occurred; Processing CHOW Applications; Intervening CHOWs; EFT Payments and CHOWs; Tie-In Notices; Out-of-State Practice Locations for Certified Providers; State Surveys and the CMS–855A; Sole Proprietorships; Additional CMS–855A Processing Instructions; Special Verification Procedures for Enrolling Independent CLIA Labs, Ambulatory Surgical Centers and Portable X-Ray Suppliers; CLIA Labs; ASCs and Portable X-Ray Suppliers; ASC/PXRS Changes of Ownership; Determining Whether a CHOW Has Occurred; EFT Payments and CHOWs; ASC/PXRS Tie-In Notices; Out-of-State Practice Locations for Certified Suppliers; State Surveys and the CMS–855B; Non-Certified Suppliers and Individual Practitioners; Certified Providers and Certified Suppliers; Approval of DMEPOS Suppliers; Non-CMS–855 Enrollment Activities; Contractor Communications; Reserved for Future Use; External Reporting Requirements; Reserved for Future Use.
234	Revision to Instructions Relating to Compliance Standards for Independent Diagnostic Testing Facilities; IDTF Standards; Supervising Physicians.
235	Additional Information on Reporting a National Provider Identifier for Ordering/Referring and Attending/Operating/Other Service Facility for Medicare; Claims.
236	Update to Chapter 10; Returning the Application; National Provider Identifier; Changes of Information; General Procedures; Changes of Information and Complete CMS–855 Applications; Incomplete or Unverifiable Changes of Information; Special Instructions for Certified Providers, ASC, and Portable X-Ray Supplies (PXRSs); Voluntary Terminations; Electronic Fund Transfers; Carrier-Enrolled Organizational Suppliers; CLIA Labs; Mammography Screening Centers; Pharmacies; Portable X-Ray Suppliers; Radiation Therapy Centers; Slide Preparation Facilities; Physicians; Physician Assistants; Psychologists Practicing Independently; Registered Dietitians; CMS or Contractor Issued Deactivations; Revocations Involving Certified Suppliers and Providers; Special Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Instructions; DMEPOS Supplier Accreditation; Enrolling Indian Health Service Facilities as DMEPOS Suppliers.
237	PIMR Annual Update; Coding T and F Codes.
238	Correction of the Medicare Contractor System Downcoding Problem in Program Integrity Management Reporting System.
239	Additional Instructions for the Execution of the Medicare Provider Enrollment; Demonstration for Home Health Agencies in High-Risk Areas.
240	Revise the Fiscal Intermediary Shared System (FISS) to Include All 11x Claims in the Nightly Universe Files Generated for the Comprehensive Error Rate Testing Program; Providing Sample Information to the Contractor.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 2008—Continued

Transmittal No.	Manual/Subject/Publication No.
241	Flagging Health Insurance Claim Numbers in the Medicare Carrier System for Pre-Payment Review/Audit; Medical Review for Benefit Integrity Purposes.
242	Items and Special Services Having Special DME Review Considerations; Rules Concerning Orders Home Use of DME; Physician Orders; Verbal and Preliminary Written Orders; Detailed Written Orders; Written Orders Prior to Delivery; Requirements of New Orders; Certificates of Medical Necessity and DME Information Forms; Completing a CMN or DIF; Cover Letters for CMNs; Reserved for Future Use; DME MACs and DME PSCs Authority to Initiate an Overpayment and/or Civil Monetary Penalty When Valid CMNs Are Identified; Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders and CMNs; Physician Assistant Rules Concerning Orders and CMNs; Documentation in the Patient's Medical Record; Supplier Documentation; Evidence of Medical Necessity; Evidence of Medical Necessity for the Oxygen CMN; Evidence of Medical Necessity: Wheelchair and Power-Operated Vehicle Claims; Period of Medical Necessity—Home Dialysis Equipment; Safeguards in Making Monthly Payments; Reserved for Future Use; Pick-up Slips; Incurred Expenses for DME and Orthotic and Prosthetic Devices; Reserved for Future Use; Items Eligible for ADMCs; Instructions for Submitting Advance Determination of Medicare Coverage Requests; Instructions Processing Advance Determination of Medicare Coverage Requests; Affirmative Advance Determination of Medicare Coverage Decision Instructions; Processing Advance Determination of Medicare Coverage Requests; DME MAC Tracking.
243	Implementation of a Program Integrity Management Reporting Edit Effectiveness; Report for Program Safeguard Contractors.
244	Collapsing Medicare Provider Transaction Access Numbers to Ensure a One-to-One; National Provider Identifier Match.
245	Processing Part B Therapy Claims While the Therapy Cap Exceptions Process is in Effect; Exception From the Uniform Dollar Limitation ("Therapy Cap").
246	Clarification of Items in Chapter 10; Practice Location Information; Certification Statement; Desk and Site Reviews; Non-Participating Emergency Hospitals and Veterans Administration Hospitals.
247	Model Letters for Provider Enrollment.
248	Signature Requirements Clarification; Documentation Specifications for Areas Selected for Prepayment or Postpayment; Medical Review.
249	Carrier Assignment of Provider Identification Numbers.
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100–09)	
21	Instructions Related to the CMS Standardized Provider Inquiry Chart for FY 2008; Data to be Reported Monthly; Provider Inquiry Reporting Standardization; Inquiry Tracking; Updates to Chart; General Requirements; Data to Be Reported Monthly; Provider Inquiry Standardized Categories.
Medicare End Stage Renal Disease Network Organizations (CMS-Pub 100–14)	
00	None.
Medicare Managed Care (CMS-Pub. 100–16)	
00	None.
Medicare Business Partners Systems Security (CMS-Pub. 100–17)	
00	None.
Demonstrations (CMS-Pub. 100–19)	
55	Medicare Acute Care Episode Demonstration.
56	Implementation of Laboratory Competitive Bidding Demonstration.
57	Laboratory Competitive Bidding Demonstration (Second Phase of Implementation).
One Time Notification (CMS-Pub. 100–20)	
308	This Transmittal is being Rescinded and Replaced by Transmittal 328.
309	New Coordination of Benefits Agreement (COBA) Editing to Address Duplicate Crossover Claim File Submissions.
310	Requirements for Including an 8-Digit Clinical Trial Number on Claims.
311	Support Income Tax Reporting.
312	EMERGENCY—Legislative Change Affecting the 2008 Medicare Physician Fee Schedule and Extension of the 2008 Participation Open Enrollment Period.
313	New Contractor Numbers for the States of Colorado, New Mexico, Oklahoma, and Texas in Jurisdiction 4 Part AB Medicare Administrative Services Workload.
314	Limitation of Recoupment—FISS Recoupment and Claims Adjustment Process.
315	BOI Extract for CWF and MBD.
316	Submitting Outpatient Provider Specific Data.
317	Production Region Split and New Contractor Number for Riverbend, New Jersey; Part A Workload.
318	Create User Account for Next Generation Desktop on Common Working File.
319	Fiscal Intermediary Shared Mid-Month Production Region Split.
320	Jurisdiction 3 Part A Merge.
321	Refinements in Cost Reporting Due to CMS' Revised Procedures for Recalibrating Relative Weights Under the Inpatient Prospective Payment System.
322	Limitation of Recoupment—FISS Recoupment and Claims Adjustment Process.
323	New Contractor Numbers for the State of California Jurisdiction 1 Part B Medicare Administrative Contractor Workload.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 2008—Continued

Transmittal No.	Manual/Subject/Publication No.
324	New Contractor Numbers for the States of Hawaii and Nevada and American Samoa, Guam, and Northern Mariana Islands Jurisdiction 1 Part B Medicare Administrative Contractor Workload.
325	New Contractor Numbers for the States of California, Hawaii, and Nevada and American Samoa, Guam, and Northern Mariana Islands Jurisdiction 1 Part A Medicare Administrative Contractor Workload.
326	Medicare Fraud Edit Module.
327	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
328	Split of HI/NV/AZ Part B Workloads and Merge of AZ/UT/MT.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER JANUARY THROUGH MARCH 2008

Publication date	FR Vol. 73 Page No.	42 CFR parts affected	File code	Title of regulation
January 3, 2008	404	414	CMS–1385–F2	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies CY 2008; Delay of Effective Date of the Anti-Markup Provisions at 42 CFR 414.50 for Certain Arrangements.
January 8, 2008	1301	422 and 423	CMS–4113–P	Medicare Program; Option for Prescription Drug Plans to Lower Their Premiums for Low-Income Subsidy Beneficiaries.
January 15, 2008	2431	410, 414, 424, and 484.	CMS–1385–F3	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Correcting Amendment.
January 15, 2008	2433	414	CMS–1385–CN3	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations (§ 414.50); Correction.
January 15, 2008	2568	409, 410, 411, 413, 414, 415, 418, 423, 424, 482, 484, and 485.	CMS–1385–CN2	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies for Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Corrections.
January 18, 2008	3405	488	CMS–2278–IFC3	Revisit User Fee Program for Medicare Survey and Certification Activities.
January 18, 2008	3546	441	CMS–2229–P	Medicaid Program; Self-Directed Personal Assistance Services Program State Plan Option (Cash and Counseling).
January 25, 2008	4503	424	CMS–6036–P	Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safteguards.
January 28, 2008	4870		CMS–3195–N	Medicare Program; Request for Nominations for Members of the Medicare Evidence Development and Coverage Advisory Committee (MedCAC).
January 28, 2008	4871		CMS–1499–N	Medicare Program; Meeting of the Practicing Physicians Advisory Council (PPAC)—March 3, 2008.
January 29, 2008	5342	412	CMS–1393–P	Medicare Program; Prospective Payment System for Long-Term Care Hospitals RY 2009: Proposed Annual Payment Rate Updates, Policy Changes, and Clarifications.
February 4, 2008	6451	400, 405, 410, 412, 413, 414, 488, and 494.	CMS–3818–RCN	Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities—Extension of Timeline for Publication of Final Rule.
February 6, 2008	6971		CMS–5014–N	Medicare Program; Rural Community Hospital Demonstration Program; Solicitation of Additional Participants.
February 22, 2008	9812		CMS–7008–N	Medicare Program; Announcement of Meeting of the Advisory Panel on Medicare Education; March 11, 2008.
February 22, 2008	9679	411 and 489	CMS–6272–F	Medicare Program; Medicare Secondary Payer (MSP) Amendments.
February 22, 2008	9672	410	CMS–6024–F	Medicare Program; Prior Determination for Certain Items and Services.
February 22, 2008	9811		CMS–3186–FN	Medicare Program; Approval of Application by the Indian Health Service (IHS) for Continued Recognition as a National Accreditation Organization that Accredits American Indian and Alaska Native (AI/AN) Entities to Furnish Outpatient Diabetes Self-Management Training.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER JANUARY THROUGH MARCH 2008—Continued

Publication date	FR Vol. 73 Page No.	42 CFR parts affected	File code	Title of regulation
February 22, 2008	9685	433	CMS–2275–F	Medicaid Program; Health Care-Related Taxes.
February 22, 2008	9727	447 and 457	CMS–2244–P	Medicaid Program; Premiums and Cost Sharing.
February 22, 2008	9714	440	CMS–2232–P	Medicaid Program; State Flexibility for Medicaid Benefit Packages.
February 22, 2008	9814		CMS–1549–N	Medicare Program; Public Meetings in Calendar Year 2008 for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations.
February 22, 2008	9807		CMS–1491–N	Medicare Program; Extension of Certain Hospital Wage Index Reclassifications.
February 22, 2008	9810		CMS–1395–N	Medicare Program; Request for Nominations to the Advisory Panel on Ambulatory Payment Classification Groups.
February 22, 2008	9860	410, 411, 412, 413, 414, 416, 419, 482, and 485.	CMS–1392–CN CMS–1533–CN CMS–1531–CN	Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; and Payments for Graduate Medical Education for Affiliated Teaching Hospitals in Certain Emergency Situations Medicare and Medicaid Programs: Hospital Conditions of Participation; Necessary Provider Designations of Critical Access Hospitals; Correction.
February 29, 2008	11043	401 and 405	CMS–4064–RCN	Medicare Program; Changes to the Medicare Claims Appeal Procedures; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule.
February 29, 2008	11120		CMS–3196–N	Medicare Program; Town Hall Meeting of the Medicare Evidence Development of Coverage Advisory Committee—April 30, 2008.
February 29, 2008	11043	488	CMS–2278–IFC4	Revisit User Fee Program for Medicare Survey and Certification Activities.
March 14, 2008	13785	447	CMS–2238–IFC	Medicaid Program; Multiple Source Drug Definition.
March 17, 2008	14342	423	CMS–4127–P	Medicare Program; Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process.
March 28, 2008	16690		CMS–2277–CN	Medicare and Medicaid Programs; Approval of the Joint Commission for Continued Deeming Authority for Home Health Agencies.
March 28, 2008	16688		CMS–2276–FN	Medicare and Medicaid Programs; Approval of the Community Health Accreditation Program for Continued Deeming Authority for Home Health Agencies.

Addendum V—National Coverage Determinations [January Through March 2008]

A national coverage determination (NCD) is a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title, or determination with respect to the amount of payment made for a particular item or service so covered. We include below all of the NCDs that were issued during the quarter covered by this notice. The entries below include information concerning completed decisions as well as sections on program and decision memoranda, which also announce pending decisions or, in some cases, explain why it was not appropriate to issue an NCD. We identify completed decisions by the section of the NCDM in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. Information on completed decisions as well as pending decisions has also been posted on the CMS Web site at *http://cms.hhs.gov/coverage.*

Title	NCDM section	TN No.	Issue date	Effective date
Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions.	110.21	R80NCD	01/14/2008	07/30/2007

Addendum VI—FDA-Approved Category B IDEs [January Through March 2008]

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved IDE. Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the **Federal Register** notice published on April 21, 1997 (62 FR 19328).

The following list includes all Category B IDEs approved by FDA during the first quarter, January through March 2008.

IDE	Category
G070016	B
G070087	B
G070116	B
G070118	B
G070137	B
G070138	B
G070155	B
G070168	B
G070191	B
G070197	B
G070202	B
G070206	B
G070219	B
G070238	B
G070240	B
G080001	B
G080005	B
G080009	B
G080014	B
G080015	B
G080018	B
G080019	B
G080021	B
G080022	B
G080025	B
G080031	B
G080032	B
G080033	B
G080034	B

Addendum VII—Approval Numbers for Collections of Information

Below we list all approval numbers for collections of information in the referenced sections of CMS regulations in Title 42; Title 45, Subchapter C; and Title 20 of the Code of Federal Regulations, which have been approved by the Office of Management and Budget:

OMB Control Numbers

Approved CFR Sections in Title 42, Title 45, and Title 20 (**Note:** Sections in Title 45 are preceded by ''45 CFR,'' and sections in Title 20 are preceded by ''20 CFR'').

OMB No.	Approved CFR sections
0938–0008	Part 424, Subpart C
0938–0022	413.20, 413.24, 413.106
0938–0023	424.103
0938–0025	406.28, 407.27
0938–0027	486.100–486.110
0938–0033	405.807
0938–0035	407.40
0938–0037	413.20, 413.24
0938–0041	408.6, 408.202
0938–0042	410.1, 410.40, 424.124, 424.601, 414.605, 414.610, 414.615, 414.620, 414.625, 424.32
0938–0045	405.711
0938–0046	405.2133
0938–0050	413.20, 413.24
0938–0062	431.151, 435.151, 435.1009, 440.220, 440.250, 442.1, 442.10–442.16, 442.30, 442.40, 442.42, 442.100–442.119, 483.400–483.480, 488.332, 488.400, 498.3–498.5
0938–0065	485.701–485.729
0938–0074	491.1–491.11
0938–0080	406.7, 406.13
0938–0086	420.200–420.206, 455.100–455.106
0938–0101	430.30
0938–0102	413.20, 413.24
0938–0107	413.20, 413.24
0938–0146	431.800–431.865
0938–0147	431.800–431.865
0938–0151	493.1–493.2001
0938–0155	405.2470
0938–0193	430.10–430.20, 440.167
0938–0202	413.17, 413.20
0938–0214	411.25, 489.2, 489.20
0938–0236	413.20, 413.24
0938–0242	488.26 and 442.30
0938–0245	407.10, 407.11
0938–0246	431.800–431.865
0938–0251	406.7
0938–0266	416.1–416.150
0938–0267	485.56, 485.58, 485.60, 485.64, 485.66
0938–0269	412.116, 412.632, 413.64, 413.350, 484.245
0938–0270	405.376
0938–0272	440.180, 441.300–441.310
0938–0273	485.701–485.729
0938–0279	424.5
0938–0287	447.31
0938–0296	413.170, 413.184
0938–0301	413.20, 413.24, 415.60
0938–0302	418.22, 418.24, 418.28, 418.56, 418.58, 418.70, 418.74, 418.83, 418.96, 418.100
0938–0313	489.11, 489.20
0938–0328	482.12, 482.13, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.45, 482.53, 482.56, 482.57, 482.60, 482.61, 482.62, 482.66, 485.618, 485.631
0938–0334	491.9, 491.10
0938–0338	486.104, 486.106, 486.110
0938–0354	441.50
0938–0355	442.30, 488.26
0938–0358	488.26
0938–0359	412.40–412.52
0938–0360	488.60
0938–0365	484.10, 484.12, 484.14, 484.16, 484.18, , 484.36, 484.48, 484.52
0938–0372	414.330
0938–0378	482.60–482.62
0938–0379	442.30, 488.26
0938–0386	405.2100–405.2171
0938–0391	488.18, 488.26, 488.28
0938–0426	480.104, 480.105, 480.116, 480.134
0938–0429	447.53
0938–0443	478.18, 478.34, 478.36, 478.42
0938–0444	1004.40, 1004.50, 1004.60, 1004.70
0938–0445	412.44, 412.46, 431.630, 476.71, 476.74, 476.78
0938–0447	405.2133
0938–0448	405.2133, 45 CFR 5, 5b; 20 CFR parts 401, 422E 0938–0449440.180, 441.300–441.310
0938–0454	424.20
0938–0456	412.105
0938–0463	413.20, 413.24, 413.106
0938–0467	431.17, 431.306, 435.910, 435.920, 435.940–435.960
0938–0469	417.126, 422.502, 422.516
0938–0470	417.143, 422.6
0938–0477	412.92
0938–0484	424.123
0938–0501	406.15
0938–0502	433.138
0938–0512	486.301–486.348
0938–0526	475.102, 475.103, 475.104, 475.105, 475.106
0938–0534	410.38, 424.5
0938–0544	493.1–493.2001
0938–0564	411.32
0938–0565	411.20–411.206
0938–0566	411.404, 411.406, 411.408
0938–0573	412.256
0938–0578	447.534
0938–0581	493.1–493.2001
0938–0599	493.1–493.2001
0938–0600	405.371, 405.378, 413.20
0938–0610	417.436, 417.801, 422.128, 430.12, 431.20, 431.107, 483.10, 484.10, 489.102
0938–0612	493.801, 493.803, 493.1232, 493.1233, 493.1234, 493.1235, 493.1236, 493.1239, 493.1241, 493.1242, 493.1249, 493.1251, 493,1252, 493.1253, 493.1254, 493.1255, 493.1256, 493.1261, 493.1262, 493.1263, 493.1269, 493.1273, 493.1274, 493.1278, 493.1283, 493.1289, 493.1291, 493.1299
0938–0618	433.68, 433.74, 447.272
0938–0653	493.1771, 493.1773, 493.1777
0938–0657	405.2110, 405.2112
0938–0658	405.2110, 405.2112
0938–0667	482.12, 488.18, 489.20, 489.24
0938–0686	493.551–493.557
0938–0688	486.301–486.325
0938–0691	412.106
0938–0692	466.78, 489.20, 489.27
0938–0701	422.152
0938–0702	45 CFR 146.111, 146.115, 146.117, 146.150, 146.152, 146.160, 146.180
0938–0703	45 CFR 148.120, 148.122, 148.124, 148.126, 148.128
0938–0714	411.370–411.389
0938–0717	424.57
0938–0721	410.33
0938–0723	421.300–421.316

OMB No.	Approved CFR sections
0938–0730	405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, 424.24
0938–0732	417.126, 417.470
0938–0734	45 CFR 5b
0938–0739	413.337, 413.343, 424.32, 483.20
0938–0749	424.57
0938–0753	422.000–422.700
0938–0754	441.151, 441.152
0938–0758	413.20, 413.24
0938–0760	484.55, 484.205, 484.245, 484.250
0938–0761	484.11, 484.20
0938–0763	422.250, 422.252, 422.254, 422.256, 422.258, 422.262, 422.264, 422.266, 422.270, 422.300, 422.304, 422.306, 422.308, 422.310, 422.312, 422.314, 422.316, 422.318, 422.320, 422.322, 422.324, 423.251, 423.258, 423.265, 423.272, 423.286, 423.293, 423.301, 423.308, 423.315, 423.322, 423.329, 423.336, 423.343, 423.346, 423.350
0938–0770	410.2
0938–0778	422.111, 422.564
0938–0779	417.126, 417.470, 422.64, 422.210
0938–0781	411.404, 484.10
0938–0786	438.352, 438.360, 438.362, 438.364
0938–0790	460.12–460.210
0938–0792	491.8, 491.11
0938–0796	422.64
0938–0798	413.24, 413.65, 419.42
0938–0802	419.43
0938–0818	410.141–410.146, 414.63
0938–0829	422.568
0938–0832	Parts 489 and 491
0938–0833	483.350–483.376
0938–0841	431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, 457.1180
0938–0842	412.23, 412.604, 412.606, 412.608, 412.610, 412.614, 412.618, 412.626, 413.64
0938–0846	411.352–411.361
0938–0857	Part 419
0938–0860	Part 419
0938–0866	45 CFR part 162
0938–0872	413.337, 483.20
0938–0873	422.152
0938–0874	45 CFR parts 160 and 162
0938–0878	Part 422 Subparts F and G
0938–0887	45 CFR 148.316, 148.318, 148.320
0938–0897	412.22, 412.533
0938–0907	412.230, 412.304, 413.65
0938–0910	422.620, 422.624, 422.626
0938–0911	426.400, 426.500
0938–0915	421.120, 421.122
0938–0916	483.160
0938–0920	438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.114, 438.202, 438.206, 438.207, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.604, 438.710, 438.722, 438.724, 438.810
0938–0921	414.804
0938–0931	45 CFR 142.408, 162.408, and 162.406
0938–0933	438.50
0938–0935	422 Subparts F and K
0938–0936	423
0938–0939	405.502
0938–0944	422.250, 422.252, 422.254, 422.256, 422.258, 422.262, 422.264, 422.266, 422.270, 422.300, 422.304, 422.306, 422.308, 422.310, 422.312, 422.314, 422.316, 422.318, 422.320, 422.322, 422.324, 423.251, 423.258, 423.265, 423.272, 423.279, 423.286, 423.293, 423.301, 423.308, 423.315, 423.322, 423.329, 423.336, 423.343, 423.346, 423.350
0938–0950	405.910
0938–0951	423.48
0938–0953	405.1200 and 405.1202
0938–0954	414.906, 414.908, 414.910, 414.914, 414.916
0938–0957	Part 423 Subpart R
0938–0964	403.460, 411.47
0938–0969	421.405
0938–0975	423.562(a)
0938–0976	423.568
0938–0977	Part 423 Subpart R
0938–0978	423.464
0938–0982	422.310, 423.301, 423.322, 423.875, 423.888
0938–0986	412.20–412.30
0938–0990	423.56
0938–0992	423.505, 423.514
0938–0993	1396
0938–0997	424.5
0938–0999	42 CFR 424 Subpart C
0938–1009	411.357(v), 411.357(w)
0938–1020	412.525(a)(4), 412.529(c)(3), 412.84(i)(2)
0938–1024	1396
0938–1026	447.52
0938–1013	423.56e
0938–1019	405.1206, 422.622
0938–1023	422.152a
0938–1034	42 CFR 489.20

Addendum VIII—Medicare-Approved Carotid Stent Facilities [January Through March 2008]

On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients.

Facility	Provider No.	Effective date	State	Additional information
Union Hospital of Cecil County, 106 Bow Street, Elkton, MD 21921	210032	01/04/2008	MD.	
Southwest Healthcare System, 36485 Inland Valley Drive, Wildomar, CA 92595	050701	01/14/2008	CA.	
Long Island College Hospital, 339 Hicks Street, Brooklyn, NY 11201	330152	02/15/2008	NY.	
Halifax Regional Health System, 2204 Wilborn Avenue, South Boston, VA 24592	490013	02/27/2008	VA.	
Montgomery Hospital, 1301 Powell Street, Norristown, PA 19404–0992	390108	02/27/2008	PA.	PO Box 992.

Addendum IX—American College of Cardiology's National Cardiovascular Data Registry Sites [January Through December 2007]

In order to obtain reimbursement, Medicare national coverage policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. This policy became effective January 27, 2005. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare National Coverage Determination (NCD) Manual, which is on the Centers for Medicare & Medicaid Services (CMS) Web site at *http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961.*

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the American College of Cardiology's National Cardiovascular Data Registry (ACC–NCDR) ICD registry. Therefore, in order for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC–NCDR ICD registry.

We maintain a list of facilities that have been enrolled in this registry. Addendum IX includes the facilities that have been designated in the quarter covered by this notice.

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Abbott Northwestern Hospital.	800 East 28th Street (Internal Zip 33210).		Minneapolis	MN	55407	612–863–6221	612–863–3771
Adena Regional Medical Center.	272 Hospital Road		Chillicothe	OH	45601	740–779–7552	
Adventist Medical Center	10123 SE Market Street		Portland	OR	97216	503–251–6172	503–251–6236
Advocate Christ Medical Center.	4440 West 95th Street	#127NOB	Oak Lawn	IL	60453	708–684–3160	708–684–3260
Advocate Good Shepherd Hospital.	450 W. Highway 22		Barrington	IL	60010	847–842–3755	847–842–2992
Advocate Illinos Masonic Medical Center.	836 W. Wellington		Chicago	IL	60657	773–296–5651	
Advocate South Suburban Hospital.	17800 S. Kedzie Avenue		Hazel Crest	IL	60429	708–213–3332	708–213–0161
Aiken Regional Medical Center.	302 University Parkway		Aiken	SC	29802	803–641–5280	803–641–5054
Akron City Hospital	525 East Market Street		Akron	OH	44309–2090	330–375–4940	330–375–7655
Akron General Medical Center.	400 Wabash Avenue	Heart & Vascular Center.	Akron	OH	44307	330–344–1119	330–434–4739
Alaska Regional Hospital	2801 Debarr Road		Anchorage	AK	99508	907–264–1899	907–264–1143
Albany Medical Center Hospital.	43 New Scotland Avenue		Albany	NY	12208	518–262–2581	518–262–2626
Albert Einstein Medical Center.	5501 Old York Road		Philadelphia	PA	19141	215–456–7013	215–456–3533
Alexian Brothers Medical Center.	800 Biesterfield Road		Elk Grove Village	IL	60007–3311	847–437–5500 x4160	847–981–2037
Alpena Regional Medical Center.	1501 W. Chisholm Street		Alpena	MI	49707	(989) 356–7360	(989) 356–7551
Alta Bates Medical Center	2450 Ashby Avenue		Berkeley	CA	94705	510–204–1758	
Alta Bates Summit Medical Center.	350 Hawthorne Avenue		Oakland	CA	94609	(510)655–4000 3894	
Alton Memorial Hospital	1 Memorial Drive		Alton	IL	62067	618–463–7621	618–463–7766
Alvarado Hospital	6645 Alvarado Road		San Diego	CA	92120	619–229–4733	619–229–7272
Anaheim Memorial Medical Ctr.	1111 W. La Palma Avenue		Anaheim	CA	92801	714–999–3931	(714) 999–6063
AnMed Health	800 Fant Street		Anderson	SC	29621	864–512–1342	864–260–3975
Appleton Medical Center/ ThedaClark Medical Center.	1818 N. Meade Street	Rm 165–B	Appleton	WI	54911	920–735–7573	920–738–6353
Arizona Heart Hospital	Arizona Heart Hospital	1930 East Thomas Road.	Phoenix	AZ	85016	602–532–1035	602–532–2000
Aspirus Wausau Hospital	333 Pine Ridge Boulevard		Wausau	WI	54401	715–847–2504	715–847–2207
Athens Regional Medical Center.	1199 Prince Avenue		Athens	GA	30606	706 475 5761	706 475 5779
Atlanticare Regional Medical Center.	2500 English Creek Avenue.		Egg Habour Township.	NJ	08234	609 748 7502	
Audrain Medical Center	620 E. Monroe Street		Mexico	MO	65265	573–582–8004	573–582–3739
Aventura Hospital and Medical Center.	20900 Biscayne Boulevard		Aventura	FL	33180	305–937–6903	305–682–7033
Avera Heart Hospital of South Dakota.	4500 West 69th Street		Sioux Falls	SD	57108	605–977–7025	605–977–7001
Avera Sacred Heart Hospital.	501 Summit		Yankton	SD	57078	605–668–8140	605–668–8058
Bakersfield Heart Hospital	3001 Sillect Avenue		Bakersfield	CA	93308	661–316–6081	661–316–6089
Ball Memorial Hospital	2401 University Avenue		Muncie	IN	47303	765–747–4284	765–747–8406
Banner Desert Medical Center.	Banner Desert Medical Center, Quality Management.	1400 S. Dobson Road.	Mesa	AZ	85202	480–512–3321	480–512–5570
Banner Estrella Medical Center.	9201 W. Thomas Road		Phoenix	AZ	85037	623–327–5311	
Banner Good Samaritan Med Center.	1111 East McDowell Road		Phoenix	AZ	85006–2612	602–239–4041	602–239–3072
Banner Heart Hospital	6750 E. Baywood Avenue		Mesa	AZ	85206	480–854–5100	480–854–5009

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Banner Thunderbird Med Center.	5555 W. Thunderbird Road		Glendale	AZ	85306	602–865–2126	602–865–4769
Baptist Health Medical Center.	3333 Springhill Drive		North Little Rock	AR	72117	501–202–3774	(501) 202–6850
Baptist Hospital	1000 W. Moreno Street		Pensacola	FL	32501	(850) 469–5881	(850) 469–5057
Baptist Hospital West	137 Blount Avenue		Knoxville	TN	37920	865–549–2651	865–549–2967
Baptist Medical Center	111 Dallas Street		San Antonio	TX	78205	210–297–1264	210–297–0926
Baptist Memorial Hospital Golden Triangle.	2520 5th Street NorthPO Box 1307.		Columbus	MS	39703	662–244–1032	662–244–1016
Baptist Memorial Hospital North Mississippi.	2301 South Lamar Boulevard.		Oxford	MS	38655	662–232–8166	662–232–8161
Baptist Memorial Hospital—Desoto.	7601 Southcrest Parkway		Southaven	MS	38671	662–349–5253	662–349–4091
Baptist Memorial Hospital—Union City.	1201 Bishop Street		Union City	TN	38261	731–884–8777	
Baptist St. Anthony's Health Systems.	1600 Wallace Boulevard		Amarillo	TX	79106	806–212–5935	
Barberton Citizens Hospital	155 5th Street NE		Barberton	OH	44203	330–615–3919	330–615–3921
Barnes Jewish Hospital/ Washington University.	#1 Barnes Jewish Hospital Plaza.	SW Tower—Main. Mailstop 90–59–315.	Saint Louis	MO	63110–9930	314–362–9404	314–362–0079
Barstow Community Hospital.	555 South Seventh Street		Barstow	CA	92311	760–957–3346	
Bassett Healthcare—(Mary Imogene Bassett Hospital).	One Atwell Road		Cooperstown	NY	13326	607–547–4808	607–547–6892
Baton Rouge General Medical Center.	3600 Florida Boulevard		Baton Rouge	LA	70806	225–381–6672	225–381–6225
Battle Creek Health System	300 North Avenue		Battle Creek	MI	49016	616–966–8165	616–966–8061
Baxter Regional Medical Center Attn: A/P.	624 Hospital Drive		Mountain Home	AR	72653	870–508–1460	
Bay Medical Center	615 North Bonita Avenue		Panama City	FL	32401	850–747–6135	850–747–6672
Bay Regional Medical Center.	1900 Columbus Avenue		Bay City	MI	48708	989–894–8616	989–893–3434
Bayfront Medical Center	701 Sixth Street South		St. Petersburg	FL	33701	727.893.6273	727.893.6930
Bayhealth Medical Center (KGH).	640 S. State Street		Dover	DE	19901	(302) 744–6636	(302) 744–6690
Baylor All Saints Medical Center at Fort Worth.	1400 8th Avenue		Fort Worth	TX	76104	817–922–1876	817–922–1236
Baylor Jack and Jane Hamilton Heart and Vascular Hospital.	621 North Hall Street		Dallas	TX	75226	214–820–0663	
Baylor Medical Center at Irving.	1901 North MacArthur Boulevard.		Irving	TX	75061	972–579–8525	972–579–8557
Baylor Regional Medical Center at Grapevine.	1650 West College Street		Grapevine	TX	76051	817–424–4793	817–329–2845
Bayshore Medical Center	4000 Spencer Highway		Pasadena	TX	77504	713–359–1379	713–359–2223
Baystate Medical Center	759 Chestnut Street	Springfield 4 4558	Springfield	MA	01199	(413) 794–5257	413–794–9294
Bellevue Hospital Center	462 First Avenue		New York	NY	10016	212–562–2227	212–562–2991
Bellin Memorial Hospital	744 S. Webster Avenue	Cardiac Data Center 5th Floor.	Green Bay	WI	54301	920–433–3785	920–433–7450
Benefis Healthcare	1101 26th Street South		Great Falls	MT	59405–5161	406–455–5693	406–455–4972
Bert Fish Medical Center	401 Palmetto Street		New Smyrna Beach.	FL	32168	386–424–5288	
Bethesda Memorial Hospital	2815 S. Seacrest Blvd		Boynton Beach	FL	33435	561–737–7733 x5422	
Biloxi Regional Medical Center.	150 Reynoir Street		Biloxi	MS	39531	228–436–1469	228–436–1580
Blake Medical Center	2020 59th Street West		Bradenton	FL	34209	941–798–6447	941–798–6439
Blanchard Valley Hospital	1900 South Main Street	HeartCare Center	Findlay	OH	45840	419.429.6485	419.427.7626
Blessing Hospital	1005 Broadway	PO Box 7005	Quincy	IL	62305–7005	217–223–8400 ext 6669	217–228–3097
Bloomington Hospital	601 W. Second Street		Bloomington	IN	47403	(812) 353–9385	(812) 353–5625
Blue Ridge HealthCare	2201 South Sterling Street		Morganton	NC	28655	828–580–6253	
Boca Raton Community Hospital.	800 Meadows Road		Boca Raton	FL	33486	561.955.4442	561.955.3244
Bon Secours—Memorial Regional Medical Center.	5801 Bremo Road	Suite 310, North Medical Office Building.	Richmond	VA	23226	804–281–8496	
Bon Secours St Francis Medical Center.		13701 Centerpointe Parkway.	Midlothian	VA	23114	804–594–3247	
Bon Secours St. Marys Hospital.	5801 Bremo Road	Suite 310, North Medical Office Building.	Richmond	VA	23226	804–281–8496	804–287–7310
Boone Hospital Center	1600 E. Broadway		Columbia	MO	65201–5897	573–815–6068	573–815–8377
Borgess Medical Center	1521 Gull Road		Kalamazoo	MI	49048	269–226–8261	269–226–7401
Boston Medical Center	One Boston Medical Place		Boston	MA		617–638–7298	
Botsford Hospital	28050 Grand River Avenue		Farmington Hills	MI	48336	248–615–7481	248–471–4400
Braddock Campus	900 Seton Drive		Cumberland	MD	21502–1850	301–723–6291	301–723–5061
Brandon Regional Hospital	119 Oakfield Drive		Brandon	FL	33511	813–571–5108	813–571–5221
Brandon Regional Hospital	119 Oakfield Drive	Attn: CCL	Brandon	FL	33511	813–571–5164	813–571–5221

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Bromenn Hospital	PO Box 2850		Bloomington	IL	61702–2850	309–268–5318	
Bronson Methodist Hospital	601 John Street		Kalamazoo	MI	49007–5348	269–341–7567	269–341–8330
Brookdale Hospital & Medical Center.	1 Brookdale Plaza		Brooklyn	NY	11212	718–240–6204	718–240–6516
Brooksville Regional Hospital.	17240 Cortez Boulevard		Brooksville	FL	34601	352–544–6034	
Bryan LGH Medical Center	1600 South 48th Street		Lincoln	NE	68526	402–481–8103	
Bryn Mawr Hospital	Suite 557 Lankenau MOB East.	100 Lancaster Avenue.	Wynnewood	PA	19096	610–526–8661	
Buffalo General Hospital/ Aaron Health Sciences Library 4D.	100 High Street		Buffalo	NY	14203	746–859–1080	716–859–3765
Cabell Huntington Hospital	1340 Hal Greer Boulevard		Huntington	WV	25701	304–526–6375	304–526–6377
California Pacific Medical Center.	2330 Clay Street, Stern Building, Room #103.	Stern Building, Room #103.	San Francisco	CA	94115	415–600–3473	415–600–5955
CAMC Teays Valley Hospital.	1400 Hospital Drive		Hurricane	WI	25526	304–757–1738	304–757–1875
Camden-Clark Memorial Hospital.	800 Garfield Avenue		Parkersburg	WV	26101	304–424–2851	304–424–2805
Candler Hospital, Inc.	5353 Reynolds Street		Savannah	GA	31405	912–819–5291	
Cape Canaveral Hospital	701 West Cocoa Beach Causeway.		Cocoa Beach	FL	32931	321–868–7612	
Cape Cod Hospital	40 Quinlan Way		Hyannis	MA	02601	(508) 862–5723	
Cape Fear Valley Health System.	303 Wagoner Drive		Fayetteville	NC	28303–4646	910–609–6552	910–609–7157
Capital Regional Medical Center.	*barbara.scott3 @hcahealthcare.com.*		Tallahassee	FL	32308	850–325–5181	
Capital Regional Medical Center.	1125 Madison Street (PO Box 1128).		Jefferson City	MO	65102–1128	573–632–5996	573–632–5999
Cardiovascular Center of Puerto Rico.	PO Box 366528		San Juan	PR	00936–6528	787–754–8500 x3058	
Carilion Roanoke Memorial Hosp.	Att: Cardiac Cath Lab	PO Box 13367	Roanoke	VA	24033–3367	540–981–8929	540–981–7010
Caritas Norwood Hospital	800 Washington Street		Norwood	MA	02062	781–278–6241	781–255–7351
Caritas St. Elizabeths Med Center.	736 Cambridge Street		Boston	MA	02135	614–789–3184	617–779–6051
Carle Foundation Hospital	611 W. Park Street		Urbana	IL	61801	217–383–4749	
Carolina Pines Regional Medical Center.	1304 W BoBo Newsom Highway.		Hartsville	SC	29550	843–339–4726	843–339–4728
Carolinas Hospital System	805 Pamplico Highway		Florence	SC	29505	843–674–2610	843–674–2683
Carolinas Medical Center	PO Box 32861		Charlotte	NC	28232	704 355–7914	
Carolinas Medical Center—Mercy.	2001 Vail Avenue	Cath Lab	Charlotte	NC	28207	704–304–5495	704–304–6132
Carondelet Heart Institute at St. Joseph Medical Center.	1000 Carondelet Drive		Kansas City	MO	64114	816–943–2732	
Carroll Hospital Center	200 Memorial Avenue		Westminster	MD	21157	410–871–7194	
Carson Tahoe Regional Medical Center.	1600 Medical Parkway		Carson City	NV	89706	775 445–8844	
Cartersville Medical Center	PO Box 20008		Cartersville	GA	30120	678–721–5582	770–606–2204
Casa Grande Regional Medical Center.	1800 E. Florence Boulevard.		Casa Grande	AZ	85222	520–381–6332	520–381–6621
Catawba Valley Medical Center.	810 Fairgrove Church Road.		Hickory	NC	28602	828–326–3863	828–326–3191
Catholic Medical Center	100 McGregor Street	Level C Room 248.	Manchester	NH	03102–3770	603–663–6971	603–663–6390
Cayuga Medical Center at Ithaca.	101 Dates Drive		Ithaca	NY	14850	607–274–4590	607–274–4588
Cedars-Sinai Health Systems.	8700 Beverly Boulevard	MGB 901	Los Angeles	CA	90048	310–423–9663	310–423–9668
Centennial Medical Center	12505 Lebanon Boulevard		Frisco	TX	75035	972–963–3168	
Centennial Medical Center	2300 Patterson Street		Nashville	TN	37203		
Centerpoint Medical Center	19600 E. 39th Street		Independence	MO	64057	816 698–7152	816 698–7151
Centinela Hospital Medical Center.	555 E. Hardy Street		Inglewood	CA	90301		
Central Baptist Hospital	1800 Nicholasville Road Suite 401.		Lexington	KY	40503	859–260–6763	859–260–6320
Central DuPage Hospital	25 N. Winfield Road		Winfield	IL	60190	630–933–6922	
Central Florida Regional Hospital.	1401W. Seminole Boulevard.		Sanford	FL	32771	407.321.4500 x5372	407–324–2155
Central Maine Medical Center.	300 Main Street		Lewiston	ME	04240	207–795–0111 x3752	207–753–3903
Central Minnesota Heart Center at St. Cloud Hospital.	1406 Sixth Ave. North		St. Cloud	MN	56303	320–251–2700 x52627	320–255–5847
Central Mississippi Medical Center.	1850 Chadwick Drive		Jackson	MS	39204	601–376–2826	601–376–1205
Chandler Regional Medical Center.	475 S. Dobson Road	Quality Management Department.	Chandler	AZ	85224	480–728–3877	602–798–0771
Charleston Area Medical Center.	501 Morris Street		Charleston	WV	25301	304–388–7980	304–388–7979
Charlotte Regional Medical Center.	809 East Marion Avenue		Punta Gorda	FL	33950	941–637–2439	941–637–2452

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Charlton Memorial Hospital	363 Highland Avenue		Fall River	MA	02720–3700	508–679–7159	508–679–7147
Chattanooga-Hamilton County Hospital Authority/ER.	975 E. Third Street		Chattanooga	TN	37403	423–778–4027	423–778–6001
Chesapeake General Hospital.	736 Battlefield Boulevard North.		Chesapeake	VA	23320	757–312–5250	
Cheshire Medical Center	580 Court Street		Keene	NH	03431	603–354–5454 ext. 3588	
Chester County Hospital	701 East Marshall Street		West Chester	PA	19380	610–738–2817	610–738–2579
Chester River Hospital Center.	100 Brown Street		Chestertown	MD	21620	410–778–3300	
Cheyenne Regional Medical Center.	Cheyenne Regional Medical Center.	214 E. 23rd Street.	Cheyenne	WY	82001	307–633–6053	307 633–6057
Christian Hospital	11133 Dunn Road		St Louis	MO	63136	314–653–5914	
Christiana Care Health System.	4755 Ogletown-Stanton Road.		Newark	DE	19718	1–302–733–5417	
Christus Hospital—St. Mary	3600 Gates Boulevard		Port Arthur	TX	77642	409–989–5255	409–989–5197
Christus Saint Elizabeth Hospital.	2830 Calder Street		Beaumont	TX	77702	409–924–6947	409–899–7010
Christus Santa Rosa Hospital.	2827 Babcock Road		San Antonio	TX	78229		
Christus Spohn Hospital Corpus Christi—Shoreline.	600 Elizabeth Street		Corpus Christi	TX	78404	361–881–3000 X17311	
Christus St. Michael Health System.	2600 St. Michael Drive		Texarkana	TX	75503	903–614–2507	903–614–6925
Christus St. Patrick Hospital	524 South Ryan Street		Lake Charles	LA	70602–3401	337–430–5464	337–491–7535
Christus—St. Frances Cabrini Hospital.	3330 Masonic Drive	Cath Lab	Alexandria	LA	71301	318–448–6992	318–448–4926
Citrus Memorial Health System.	502 W. Highland Boulevard.		Inverness	FL	34452	352–344–6421	352–726–6729
CJW Medical Center	7101 Jahnke Road		Richmond	VA	23225–4044	(804)228–6723	(877)850–1735
Clarian Health Partners—Methodist Hospital campus.	1701 N. Senate Boulevard	Room A1082	Indianapolis	IN	46202	317–962–3583	317–962–5360
Clarian North Medical Center.	11725 Illinois Street B–178		Carmel	IN	46032	317–688–3014	317–688–2704
Clark Memorial Hospital	1220 Missouri Avenue		Jeffersonville	IN	47130	812–283–2284	
Clear Lake Regional Medical Center.	500 Medical Center Boulevard.		Webster	TX	77598	281–338–3879	281–338–3843
Cleveland Clinic Florida	3100 Weston Road		Weston	FL	33331	954–689–5265	954–689–5297
Cleveland Clinic Foundation	9500 Euclid Avenue		Cleveland	OH	44195	216–444–9214	216–445–7326
Coliseum Medical Centers	350 Hospital Drive		Macon	GA	31217	478–464–1641	478–464–1642
College Station Medical Center.	1604 Rock Prairie Road		College Station	TX	77845	979–680–5337	979–764–5108
Columbia Hospital	2025 E. Newport Avenue		Milwaukee	WI	53211	414–961–5004	414–961–5542
Columbia Regional Hospital	404 Keene Street		Columbia	MO	65201	573–875–9406	573–875–9090
Columbia St. Mary's Hospital Milwaukee.	4425 N. Port Washington Road.		Milwaukee	WI	53212	414–326–2390	414–326–2395
Columbia St. Mary's Hospital Ozaukee.	13111 N. Port Washington Road.		Mequon	WI	53097	414–326–2390	414–326–2395
Columbus Regional Hospital.	2400 17th Street		Columbus	IN	47201	812–375–3840	812–375–3833
Comanche County Memorial Hospital.	3401 W. Gore Boulevard	PO Box 129	Lawton	OK	73505	580–585–5587	
Community Health Partners	3700 Kolbe Road		Lorain	OH	44053	440–960–3495	
Community Hospital	2615 E. High Street		Springfield	OH	45505	937–328–9319	937–328–8788
Community Hospital	The Community Hospital	901 MacArthur Boulevard.	Munster	IN	46321	219–836–4501	219–852–6436
Community Hospital and Wellness Center.	433 West High Street		Bryan	OH	43506	419–636–1131 x1057	419–630–2193
Community Hospital East	Cardiovascular Services	1500 North Ritter Avenue.	Indianapolis	IN	46219	317–355–2058	327–351–7866
Community Hospital of the Monterey Peninsula.	PO Box HH		Monterey	CA	93942–1085	831–625–4553	831–625–4877
Community Hospital South	1500 N. Ritter Avenue		Indianapolis	IN	46219–3027	317–355–2058	
Community Medical Center	2827 Fort Missoula Road		Missoula	MT	59804	406 327–4646	406 327–4666
Community Medical Center	1800 Mulberry Street		Scranton	PA	18510	570–969–8219	
Community Medical Center—Clovis.	2755 Herndon Avenue		Clovis	CA	93611	559–324–4747	559–324–4004
Community Memorial Hospital.	147 N. Brent Street		Ventura	CA	93003	805–652–5617	805–585–3046
Community Memorial Hospital.	W180 N8085 Town Hall Road.		Menomonee Falls	WI	53052	414–805–4201	
Concord Hospital	250 Pleasant Street		Concord	NH	03301	603–230–6029	603–228–7342
Condell Medical Center	801 S. Milwaukee Avenue		Libertyville	IL	60048	847–990–5872	847–362–1721
Conroe Regional Medical Center.	504 Medical Center Boulevard.		Conroe	TX	77304	936–538–2779	936–538–2649
Covenant Heart Institute	3615 19th Street		Lubbock	TX	79410	806–825–4553	806–723–7311
Conway Regional Medical Center.	2302 College Avenue		Conway	AR	72034–6226	501–513–5728	501–513–5811
Cookeville Regional Medical Center.	142 W. 5th Street		Cookeville	TN	38501–1760	931–646–2784	931–646–2185
Cooley Dickinson Hospital	30 Locust Street		Northampton	MA	01060	413–582–4701	413–582–4717

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Cooper University Hospital	One Cooper Plaza	D386B	Camden	NJ	08103	856–968–7630	
Coral Gables Hospital	3100 Douglas Road		Coral Gables	FL	33134	305–460–1813	305–460–8689
Corpus Christi Medical Center.	7101 SPID		Corpus Christi	TX	78412	361–761–2738	361–761–2656
County of Santa Clara	751 S. Bascom Avenue		San Jose	CA	95128	408–885–4362	408–793–5820
Covenant Healthcare	1447 N. Harrison Street		Saginaw	MI	48602	989 583–6544	
Covenant Medical Center	3421 West Ninth Street.		Waterloo	IA	50702	319 272–5171	319–272–7536
Cox Medical Center South	3801 S. National Avenue		Springfield	MO	65807	417–269–6241	417–269–4995
Craven Regional Medical Center.	2000 Neuse Boulevard	PO Box 12157	New Bern	NC	28560	252–633–8236	252–633–8271
Creighton University Medical Center.	601 N. 30th Street		Omaha	NE	68131	402–449–4078	402–449–4475
Crestwood Medical CenterTriad Hospitals, Inc.	One Hospital Drive		Huntsville	AL	35801–3495	256–429–5628	
Crittenton Hospital Medical Center.	1101 W. University Drive		Rochester	MI	48307–1831	248.652.5612	248.652.5879
Crouse Hospital	736 Irving Avenue		Syracuse	NY	13210	315–470–7122	315–470–2958
Crozer Chester Medical Center.	1 Medical Center Boulevard.		Chester	PA	19013–3995	610–447–2306	610–447–2924
CVPH Medical Center	75 Beekman Street		Plattsburgh	NY	12901	518–562–7798	518–562–7795
Cypress Fairbanks Medical Center.	10655 Steepletop Drive		Houston	TX	77065	281–897–3544	281–897–3543
Dameron Hospital	525 W. Acacia Street		Stockton	CA	95203	209–242–7027	209–461–7534
Danbury Hospital	24 Hospital Avenue	Cardiology 2 South.	Danbury	CT	06810	203–739–6945	203–739–1667
Davis Hospital	1600 West Antelope Drive		Layton	UT	84041	801–807–7270	
Davis Regional Medical Center.	218 Old Mocksville Road		Stateville	NC	28625	704–838–7082	
Dayton Heart Hospital	707 S. Edwin C. Moses Boulevard.		Dayton	OH	45408	937–221–8056	937–221–8001
DCH Regional Medical Center.	809 University Boulevard E		Tuscaloosa	AL	35401–2029	205–759–7346	205–343–8234
Deaconess Billings Clinic	2800 9th Avenue, North		Billings	MT	59101	406–657–4336	406–657–3843
Deaconess Hospital	311 Straight Street		Cincinnati	OH	45219	513–559–2265	
Deaconess Hospital	5501 N. Portland Avenue		Oklahoma City	OK	73112	405 604–4166	
Deaconess Hospital	600 Mary Street		Evansville	IN	47747	812–450–7460	812–450–7258
Deaconess Medical Center	W. 800 Fifth Avenue		Spokane	WA	99204	509–473–7303	
Deborah Heart & Lung Center.	200 Trenton Road		Browns Mills	NJ	08015	609–893–1200 x5800	609–893–5953
Decatur General Hospital	1201 7th Street		Decatur	AL	35601	256–341–2890	
Degraff Memorial Hospital	100 High Street		Buffalo	NY	14203	716–859–1080	716–859–3765
Dekalb Regional Medical Center.	200 Medical Center Drive		Fort Payne	AL	35968	256–997–2158	
Del Sol Medical Center	10301 Gateway West		El Pasoq	TX	79925	915–595–9632	915–595–9633
Delray Medical Center	5352 Linton Boulevard		Delray Beach	FL	33484	561–594–3278	561–495–3467
Delta Regional Medical Center.	1400 E. Union Street		Greenville	MS	38702	662–725–2053	
Denton Regional Medical Center.	3535 South I–35E		Denton	TX	76205	940–384–3875	940–384–4707
Denver Health Medical Center.	777 Bannock Street		Denver	CO	80204	303–436–5651	303–436–7739
DePaul Health Center	12303 DePaul Drive		Bridgeton	MO	63044	314–344–6790	
Des Peres Hospital	2345 Dougherty Ferry Road.		St. Louis	MO	63122	314–966–9468	
Desert Regional Medical Center.	1150 N. Indian Canyon		Palm Springs	CA	92262	760–323–6799	760–323–6725
Desert Springs Hospital	620 Shadow Lane		Las Vegas	NV	89106	702–388–8494	
Desert Valley Hospital	16850 Bear Valley Road		Victorville	CA	92392	760–241–8000 ext. 8674	760–843–5063
DeTar Hospital	506 E. San Antonio Street		Victoria	TX	77902	361–788–6991	361–788–6137
Dixie Regional Medical Center.	1380 E. Medical Drive		St. George	UT	84790	435–251–1906	435–251–1950
Doctors Hospital	9440 Poppy Drive		Dallas	TX	75218	214–324–6355	
Doctor's Hospital	3983 I–49 S. Service Road		Opelousas	LA	70570	337–948–2316	337–948–2216
Doctors Hospital at Renaissance.	5501 S. McColl Road		Edinburg	TX	78539	956 661–7760	
Doctors Hospital—Augusta	3651 Wheeler Drive		Augusta	GA	30909	706–651–6672	
Doctors Hospital of Laredo	10700 McPherson Road		Laredo	TX	78045	956–523–2009	
Doctors Hospital of Sarasota.	5731 Bee Ridge Roadq		Sarasota	FL	34233	941–342–1100	
Doctors Hospital of Stark	400 Austin Avenue		Massillon	OH	44646	330 837–7200	
Doctors Medical Center	2000 Vale Road		San Pablo	CA	94806	510–970–5184	
Doctors Medical Center	1441 Florida Avenue		Modesto	CA	95350	209–576–3603	
Dominican Santa Cruz Hospital.	1555 Soquel Drive		Santa Cruz	CA	95065	831–462–7243	831–462–7558
Downey Regional Medical Center.	11500 Brookshire Avenue		Downey	CA	90241	562–904–5034	
Doylestown Hospital	595 West State Street		Doylestown	PA	18901	215–345–2928	215–345–2411
DuBois Regional Medical Center.	100 Hospital Avenue		DuBois	PA	15801	814–375–7702	
Duke University Hospital	Erwin Road DUMC 3943		Durham	NC	27710	919–681–4060	
Dunn Memorial Hospital	1600 23rd Street		Bedford	ID	47421	812–276–1370	812–276–1034

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Durham Regional Hospital	3634 Roxboro Road		Durham	NC	27704	919–470–6344	
East Alabama Medical Center.	2000 Pepperall Parkway		Opelika	AL	36830	334–528–1748	334–528–1764
East Georgia Regional Medical Center.	1499 Fair Road (PO Box 1048).		Statesboro	GA	30459	912–486–1530	
East Jefferson General Hospital.	4200 Houma Boulevard	Quality Management Department.	Metairie	LA	70006	504–456–8449	504–454–5256
East Ohio Regional Hospital.	90 N. 4th Street		Martins Ferry	OH	43935	740–633–4156	
East Texas Medical Center	1000 S. Beckham Avenue		Tyler	TX	75711	903–535–6397	903–535–6597
Eastern Idaho RMC	3100 Channing Way		Idaho Falls	ID	83404	208–529–7394	208–529–7092
Eastern Maine Medical Center.	489 State Street	PO Box 404	Bangor	ME	04402–0404	207–973–8160	207–750–2174
Easton Hospital (Northampton Hospital Corp.).	250 South 21st Street		Easton	PA	18042	610–250–4984	(610) 250–4896
Edward Hospital	120 Spalding Drive #205		Naperville	IL	60540	630–527–3990	630–527–2888
Eisenhower Medical Center	39000 Bob Hope Drive		Rancho Mirage	CA	92270	760–674–3811	760–773–4336
El Camino Hospital	2500 Grant Road		Mountain View	CA	94040		
Eliza Coffee Memorial Hospital.	603 West College Street		Florence	AL	35630	256–768–9451	
Elkhart General Hospital	600 East Boulevard	3 South Suites	Elkhart	IN	46514–2499	574–296–6539	574–523–3495
Elliot Hospital	1 Elliot Way		Manchester	NH	03103	603 663–2959	
Ellis Hospital	1101 Nott Street		Schenectady	NY	12308	(518) 243–1943	(518) 243–4459
Elmhurst Hospital Center	79–01 Broadway	Dept of Cardiology, Suite D–54.	Elmhurst	NY	11373	(718) 334–1192	(718) 334–5990
Elmhurst Memorial Hospital Marquardt Memorial Lib.	200 Berteau Avenue		Elmhurst	IL	60126	630–833–1400 x 41431	630–782–0724
EMH Regional Medical Center.	630 East River Street		Elyria	OH	44035	440–329–7486	440–329–7470
Emory Crawford Long Hospital.	550 Peachtree Street		Atlanta	GA	30308	404–686–3671	404–686–3891
Emory Eastside Medical Center.	1700 Medical Way	(PO Box 587)	Snellville	GA	30078	770–736–2358	
Emory University Hospital	1364 Clifton Road, NE C408.		Atlanta	GA	30322	(404) 727–0750	(404) 712–1846
Encino-Tarzana Regional Medical Center.	18321 Clark Street		Tarzana	CA	91356–3501	818–708–5349	818–708–5563
Englewood Hospital & Medical Center.	350 Engle Street		Englewood	NJ	07631	201–894–3636	201 541 2188
Enloe Medical Center	1600 Esplanade		Chico	CA	95926	530–332–7432	
Erie County Medical Center	462 Grider Street		Buffalo	NY	14215	716–898–5450	
Evanston Hospital	2650 Ridge Ave		Evanston	IL	60201	847–570–2418	
Excela Health Westmoreland Hospital.	532 West Pittsburgh Street		Greensburg	PA	15601	724–832–4402	
Exempla Good Samaritan Medical Center.	2420 W. 26th Avenue Building D Suite 100.		Denver	CO	80211	303–813–5040	303–813–5055
Exempla Lutheran Medical Center.	2420 W. 26th Avenue Building D Suite 140.		Denver	CO	80211	303–813–5038	
Exempla Saint Joseph Hospital.	2420 W. 26th Avenue Building D Suite 140.		Denver	CO	80211	303–813–5040	303–813–5055
Exeter Hospital	5 Alumni Drive		Exeter	NH	03833	603 580–7484	603–580–7263
Fairfield Cardiac Cath Labs	3000 Mack Road	Suite 200	Fairfield	OH	45014	513–870–7106	513–603–8478
Fairfield Medical Center	401 N. Ewing Street		Lancaster	OH	43130	740–687–8496	740–687–8646
Fairview Hospital	18101 Lorain Road #329		Cleveland	OH	44111	216–476–7872	216–476–7097
Fairview Park Hospital	200 Industrial Boulevard		Dublin	GA	31021	478–274–3300	478–274–3191
Fairview Southdale Hospital	6401 France Avenue South.		Edina	MN	55435	952–924–5147	952–924–5012
Faith Regional Health Services.	2700 W. Norfolk Avenue		Norfolk	NE	68701	402–371–4880	402–644–7613
Fawcett Memorial Hospital	21298 Olean Boulevard		Port Charlotte	FL	33949–4960	941–629–1181 x6816	941–629–5467
FirstHealth Moore Regional Hospital.	155 Memorial Drive		Pinehurst	NC	28374	910–715–1591	910–715–2179
Fisher-Titus Medical Center	272 Benedict Avenue		Norwalk	OH	44857	419–668–8101 ext. 6475	419–660–2715
Flagler Hospital	400 Health Park Boulevard		St. Augustine	FL	32086	904–819–4404 ext 3659	
Fletcher Allen Health Care	111 Colchester Avenue		Burlington	VT	05401	802–847–5501	802–847–3031
Flordia Hospital Zephyrhills	7050 Gall Boulevard		Zephyrhills	FL	33541	813–783–6119 ext 2274	
Florida Hospital	220 Winter Park Street		Orlando	FL	32803	407–303–5600 x3669	407–303–7304
Florida Hospital Ormond Memorial.	875 Sterthaus Avenue		Ormond Beach	FL	32174	386–676–6135	386–671–6671
Florida Hospital Waterman, Inc..	1000 Waterman Way		Tavares	FL	32778	352–253–3483	352–253–3153
Florida Medical Center	5000 W. Oakland Park Boulevard.		Lauderdale Lakes	FL	33313	954–735–6000 x4309	
Flowers Hospital	4370 West Main Street		Dothan	AL	36305	334–794–5000 x8280	
Floyd Medical Center	304 Turner McCall Boulevard.		Rome	GA	30165	706–509–5000	

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Forest Hills Hospital	102–01 66th Road		Forest Hills	NY	11375		
Forrest General Hospital	6051 Highway 49 South		Hattiesburg	MS	39404–6389	601–288–2819	601–288–2808
Forsyth Medical Center	3333 Silas Creek Parkway	Clinical Improvement Box 102.	Winston-Salem	NC	27103	336–718–6370	336–277–9269
Fort Sanders Regional Medical Center.	1901 Clinch Avenue		Knoxville	TN	37916–2307	865–541–1414	865–541–2893
Fort Walton Beach Medical Center.	1000 Mar Walt Drive		Fort Walton Beach.	FL	32547	850–315–7817	
Forum Health—Northside Medical Center.	500 Gypsy Lane		Youngstown	OH	44501–0240	330–884–3021	330–884–5748
Fountain Valley Regional Hosp.	17100 Euclid Street		Fountain Valley	CA	92708–4004	714–966–8043	714–966–3327
Frankford Hospital	Knights & Red Lion Roads		Philadelphia	PA	19114	215–612–4580	215–612–5463
Frankfort Regional Medical Center.	299 Kings Daughter Drive		Frankfort	KY	40601	502–226–7698	502–226–7680
Franklin Square Hospital	9000 Franklin Square Drive.		Baltimore	MD	21237	443–777–7446	
Frederick Memorial Hospital	400 W. Seventh Street		Frederick	MD	21710	240–566–3269	
Freeman Hospital	1102 W. 32nd Street		Joplin	MO	64804	417–347–3066	417–347–3764
Freeport Health Network	1045 W. Stephenson Street.		Freeport	IL	61032	815–599–6384	
Fremont Area Medical Center.	450 East 23rd Street		Fremont	NE	68025	402–727–3659	402–727–3688
French Hospital Medical Center.	1911 Johnson Avenue		St Luis Obispo	CA	93401		
Fresno Community Hospital and Medical Center.	110 N. Valeria Street #103		Fresno	CA	93710	559–459–6771	559–459–2358
Fresno Heart Hospital	15 East Audubon Drive		Fresno	CA	93720	559–433–8026	559–433–8326
Froedtert Hospital	9200 W. Wisconsin Avenue.		Milwaukee	WI	53226	414–769–4201	414–805–4265
Frye Regional Medical Center.	420 N. Center Street		Hickory	NC	28601	828–315–5024	
Gadsden Regional Medical Center.	1007 Goodyear Avenue		Gadsden	AL	35903	256–494–4265	
Galichia Heart Hospital	2610 N. Woodlawn Boulevard.		Wichita	KS	67220	316–858–2930	316–858–8999
Garden City Hospital	6245 Inkster Road		Garden City	MI	48135	734–458–3251	734–458–3239
Gaston Memorial Hospital	2525 Court Drive		Gastonia	NC	28054	704–834–3605	704–834–4678
Gateway Medical Center Gateway Health System.	1771 Madison Street		Clarksville	TN	37043	931–551–1662	
Gateway Regional Medical Center.	2100 Madison Avenue		Granite City	IL	62040	618–798–3623	618–798–3579
Geisinger Medical Center	100 North Academy Avenue.		Danville	PA	17822–2160	570–271–5555 x54807	570–271–8056
Geisinger Wyoming Valley Medical Center.	100 North Academy Avenue.		Danville	PA	17822–2160	570–271–5555 x54807	570–271–8056
Genesis Medical Center	1236 East Rusholme Street.	Suite 190	Davenport	IA	52803–2459	563–421–3935	563–421–3933
Genesis Medical Center, Illini Campus.	801 Illini Drive		Silvis	IL	61282	309–792–7071	309–792–6424
Genesys Regional Medical Center.	One Genesys Parkway		Grand Blanc	MI	48439	810–606–7653	810–606–6668
Georgetown University Hospital.	3800 Reservoir Road NW		Washington	DC	20007	202–444–8619	202–444–3165
Glendale Adventist Medical Center.	1509 Wilson Terrace		Glendale	CA	91206	818–409–8258	818–546–5616
Glendale Memorial Hospital and Health Center.	1420 S. Central Avenue		Glendale	CA	91204	818–502–1900 x4755	818–507–4161
Glens Falls Hospital	100 Park Street		Glens Falls	NY	12801	518–926–4170	518–926–4169
Good Samaritan Heart Center.	520 South 7th Street		Vincennes	IN	47591	812–885–3964	812–885–3915
Good Samaritan Hospital and Health Center.	2222 Philadelphia Drive		Dayton	OH	45406	937–278–6251 x2256	937–341–8691
Good Samaritan Hospital	2425 Samaritan Drive	2425 Samaritan Drive.	San Jose	CA	95124	408–559–2189	408–559–2692
Good Samaritan Hospital	605 N. 12th Street		Mount Vernon	IL	62864	618–241–4438	618–241–3853
Good Samaritan Hospital	3815 Highland Avenue		Downers Grove	IL	60515	630–275–1403	603–275–5713
Good Samaritan Hospital	375 Dixmyth Avenue		Cincinnati	OH	45220–2489	513–872–4893	513–872–4897
Good Samaritan Hospital	1225 Wilshire Boulevard		Los Angelos	CA	90017	213–977–4058	213–977–2371
Good Samaritan Hospital	10 East 31 Street		Kearney	NE	68848	308–865–7516	308–865–2918
Good Samaritan Hospital	255 Lafayette Avenue		Suffern	NY	10901	845–368–5915	845 368 8250
Good Samaritan Hospital Cardiology.	1000 Montauk Highway		West Islip	NY	11795	631–376–4090	631–376–4061
Good Samaritan Hospital of Maryland.	5601 Loch Raven Boulevard.		Baltimore	MD	21239	410–532–4570	410–532–4572
Good Samaritan Medical Center.	1309 North Flagler Drive		West Palm Beach	FL	33401	561–671–7444	561–650–6186
Good Samaritan Regional Medical Center.	3600 NW Samaritan Drive		Corvallis	OR	97330	541–768–5265	541–768–4776
Good Shepherd Medical Center.	700 East Marshall Avenue		Longview	TX	75601	903–315–5118	
Governor Juan F. Luis Hospital & Medical Center.	4007 Estate Diamond Ruby.		Christiansted	VI	00820	340–778–6311	340–772–7414

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Grady Memorial Hospital	561 West Central Avenue		Delaware	OH	43015–1489	740–368–5286	
Grandview Medical Center	405 Grand Avenue		Dayton	OH	45405	937–723–3335	
Grant Medical Center	111 S. Grant Avenue		Columbus	OH	43215	614–566–9474	
Great Plains Regional Medical Center.	Box 2339		Elk City	OK	73648	580–225–2511	580–821–5541
Greater Baltimore Medical Center.	GBMC—Cardiac Cath Lab	6701 N. Charles Street.	Towson	MD	21204	443–849–2269	443–849–8154
Greenville Memorial Hospital.	701 Grove Road		Greenville	SC	29605	864–455–6464	864–455–4775
Greenwich Hospital	5 Perryridge Road		Greenwich	CT	06830	203–863–3689	
Gulf Coast Medical Center	449 W. 23rd Street		Panama City	FL	32406–5309	850–747–7896	
Gulf Coast Medical Center	1400 Highway 59		Wharton	TX	77488	979–282–6115	979–282–6163
Gundersen Lutheran Medical Center, Inc..	1900 South Avenue	H06–004	LaCrosse	WI	54601	608–775–6398	608–775–4802
Gwinnett Hospital System	1000 Medical Center Boulevard.		Lawrenceville	GA	30045	678–442–4534	
Hackensack University Medical Center.	30 Prospect Avenue		Hackensack	NJ	07601	201–996–2663	
Hackley Hospital General Fund.	1700 Clinton Street		Muskegon	MI	49443	231–728–4629	231–728–5781
Hahnemann University Hospital.	230 N. Broad Street		Philadelphia	PA	19102	215–762–2049	
Halifax Medical Center	303 N. Clyde Morris Boulevard.		Daytona Beach	FL	32114–2732	386–756–2143	386–254–2934
Halifax Regional Hospital	2204 Wilborn Avenue		South Boston	VA	24592	434–517–3457	434–517–3168
Hamilton Medical Center	1200 Memorial Drive		Dalton	GA	30720	706–272–6022	706–272–6341
Hamot Medical Center	201 State Street		Erie	PA	16550	814–877–2960	814–877–5696
Hannibal Regional Hospital	6000 Hospital Drive		Hannibal	MO	63401	573–248–5290	
Harbor Hospital Center	3001 S. Hanover Street		Baltimore	MD	21225	410–350–3898	
Hardin Memorial Hospital	913 N Dixie Avenue		Elizabethtown	KY	42701	270–706–1159	270–706–1159
Harlingen Medical Center	5501 South Expressway 77.		Harlingen	TX	78550	956–365–1140	956–365–1875
Harper University Hospital	3990 John R. Street		Detroit	MI	48201	313–745–8349	319–966–5130
Harris Methodist Fort Worth		1301 Pennsylvania Avenue.	Fort Worth	TX	76104	817–250–2780	817–250–2752
Harris Methodist HEB	1600 Hospital Parkway		Bedford	TX	76022	817–685–4081	
Harrison Medical Center	2520 Cherry Avenue		Bremerton	WA	98310	360–792–6808	
Hartford Hospital	80 Seymour Street		Hartford	CT	06102–8000	860–545–1522	860–545–3557
Harton Regional Medical Center.	1801 N. Jackson Street		Tullahoma	TN	37388	931–393–7933	
Havasu Regional Medical Center.	101 Civic Center Lane		Lake Havasu City	AZ	86403	928–453–0806	928–453–0807
Hawaii Medical Center East, LLC.	2230 Liliha Street		Honolulu	HI	96817	808–547–6434	808–547–6351
Hawaii Medical Center West.	91–2141 Fort Weaver Road.		Ewa Beach	HI	96706	808–678–7150	808–678–7163
Hays Medical Center	2220 Canterbury Road		Hays	KS	67601	785–623–5051	785–623–5052
Hazard ARH Regional Medical Center.	100 Medical Center Drive		Hazard	KY	41701	606–439–6827	
Health Care Authority for Baptist Health.	2105 East South Boulevard.		Montgomery	AL	36116	334–286–3327	334–286–2364
Heart and Lung Clinic	900 East Broadway Box 5510.		Bismarck	ND	58502	701–530–7506	701–530–7494
Heart Center of Indiana	8333 Nabb Road Suite 330	Suite 330	Indianapolis	IN	46290	317–338–6012	317–338–6214
Heart Hospital of Austin	3801 N. Lamar Boulevard		Austin	TX	78756	512–407–7497	
Heart Hospital of Lafayette	1105 Kaliste Saloom Road		Lafayette	LA	70508	337–521–1025	337–521–1006
Heart Hospital of New Mexico.	504 Elm Street NE		Albuqerque	NM	87102	505–724–2029	
Heart of Florida Regional Medical Center.	40100 Highway 27		Davenport	FL	33837	863–419–2330	
Heartland Regional Medical Center.	3333 W. Deyoung Street		Marion	IL	62959	618–998–7491	
Heartland Regional Medical Center.	The Heart Center—Cardiac Cath Lab.	5325 Faraon Street.	Saint Joseph	MO	64506–3373	816–271–6665	816–271–1077
Helen Ellis Memorial	1395 South Pinella Avenue		Tarpon Springs	FL	34689	727–942–5110	
Hellen Keller Hospital	1300 South Montgomery Avenue.		Sheffield	AL	35660	256–386–4194	256–386–4687
Hemet Valley Medical Center.	1117 E. Devonshire Avenue.		Hemet	CA	92543	(951) 652–2811	
Hendersonville Medical Center.	355 New Shackle Island Road.		Hendersonville	TN	37075	615–338–1450	615–338–1455
Hendrick Medical Center	1900 Pine Street		Abilene	TX	79601	915–670–2000	
Hennepin County Medical Center.	701 Park Avenue		Minneapolis	MN	55415–1829	612–873–3349	612–904–4222
Henrico Doctors Hospital	1602 Skipwith Road	Cardiac Cath Lab	Richmond	VA	23229	804–289–5633	804–285–5143
Henry Ford Hospital	2799 W. Grand Boulevard	K–14	Detroit	MI	48202	313–916–4905	313–916–1249
Henry Ford Macomb	15855 Nineteen Mile Road		Clinton Township	MI	48038	586 263 2108	586 263 2925
Henry Ford Macomb-Warren.	13355 East Ten Mile Road		Warren	MI	48089	586–759–7400	
Henry Mayo Newhall Memorial Hospital.	23845 McBean Parkway		Valencia	CA	91350	661–253–8023	661–253–8142
Henry Medical Center, Inc	1133 Eagles Landing Parkway.		Stockbridge	GA	30281	678–604–5027	678–604–5071

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Hialeah Hospital	651 East 25th Street		Hialeah	FL	33013	305–835–4136	305–835–4355
High Point Regional Hospital.	601 N. Elm Street		High Point	NC	27261	336–878–6006	
Highland Park Hospital	718 Glenview Avenue		Highland Park	IL	60035	847–480–2641	847–926–5332
Highlands Regional Medical Center.	3600 S. Highlands Avenue		Sebring	FL	33870	863–381–6101	
Highlands Regional Medical Center.	5000 US 321		Prestonburg	KY	41653	606–886–7481	606–886–7799
Hillcrest Baptist Medical Center.	3000 Herring Avenue		Waco	TX	76708	254–202–6849	254–202–5609
Hillcrest Hospital	6780 Mayfield Road		Mayfield Heights	OH	44124	440–312–8573	440–312–6929
Hillcrest Medical Center	1120 S. Utica Avenue	3 West	Tulsa	OK	74104	918–579–3396	918–579–5355
Hilton Head Regional Medical Center.	25 Hospital Center Boulevard.		Hilton Head	SC	29925	843–689–8359	
Hinsdale Hospital	120 N. Oak Street		Hinsdale	IL	60521	630–856–6164	
HMA-Physician Management Region 25 Disb. Acct. (Physician's Regional).	6101 Pine Ridge Road		Naples	FL	34119	239–304–4733	
Hoag Memorial Hospital Presbyterian.	One Hoag Drive		Newport Beach	CA	92658	949–764–6813	949–764–1492
Holland Community Hospital.	602 Michigan Avenue		Holland	MI	49423	616–394–3596	616–394–4207
Holmes Regional Medical Center.	1355 South Hickory Street Suite 203.		Melbourne	FL	32901	321–434–1266	321–434–7124
Holy Cross Hospital	4725 N. Federal Highway		Ft. Lauderdale	FL	33308	954–229–7968	954–267–6696
Holy Cross Hospital	2701 W. 68th Street		Chicago	IL	60629	773–884–7752	773–884–8004
Holy Cross Hospital Medical Library.	1500 Forest Glen Road		Silver Spring	MD	20910	301–754–7389	301–754–7386
Holy Spirit Health System	503 N 21st Street	Heart Center Administration.	Camp Hill	PA	17011–2204	717–972–4745	717–972–7581
Hospital of St. Raphael	Cardiac Cath Lab, 1450 Chapel Street.		New Haven	CT	06511	203–789–3460	203–867–5204
Hospital of the University of Pennsylvania.	9011 E. Gates 3400 Spruce Street.		Philadelphia	PA	19104	215–662–7781	215–349–5799
Houston Northwest Medical Center Accounts Payable.	710 FM 1960 Road West		Houston	TX	77090	281–440–2886	
Howard County General Hospital.	5755 Cedar Lane		Columbia	MD	21044	410–884–4544	410–884–4677
Howard University Hospital	2041 Georgia Avenue NW		Washington	DC	20060	202–865–6835	202–865–4449
Huguley Memorial Medical Center.	11801 S. Freeway		Ft. Worth	TX	76115	817–551–2542	817–551–2568
Huntington Hospital	100 W. California Boulevard.		Pasadena	CA	91109	626–397–2229	626–397–2191
Huntington Hospital	270 Park Avenue		Huntington	NY	11743	631–351–2798	631–351–4115
Huntsville Hospital	101 Sivley Road		Huntsville	AL	35801	256–265–2552	256–265–2291
Hutchinson Hospital	1701 E. 23rd Avenue		Hutchinson	KS	67502	620–665–2061	
Iberia Medical Center	2315 East Main Street		New Iberia	LA	70560	337–374–7192	
Immanuel—St. Joseph's Hospital.	1025 Marsh Street		Mankato	MN	56001	507–317–4328	507–389–4774
Indian River Medical Center	1000 36th Street		Vero Beach	FL	32960	772–567–4311 x1810	
Indiana Heart Institute	8333 Naab Rd, Suite 330		Indianapolis	IN	46260	317–338–6500	317–338–6214
Indiana Regional Medical Center Cardiology Department.	835 Hospital Road		Indiana	PA	15701	724–357–8035	724–357–8038
Ingalls Hospital	One Ingalls Drive		Harvey	IL	60426	708–333–2300	708–915–3114
Ingham Regional Medical Center.	401 W. Greenlawn Avenue		Lansing	MI	48910	517–334–2720	517–367–5676
Innovis Health	3000 32nd Avenue SW		Fargo	ND	58104	701–364–8263	701–364–8262
Inova Alexandria Hospital	4320 Seminary Road		Alexandria	VA	22304	703–504–7950	
Inova Fairfax Hospital/Inova Heart & Vascular Institute.	3300 Gallows Road		Falls Church	VA	22042	703–208–6694	703–208–6699
Inova Loudoun Hospital	44035 Riverside Parkway	Suite 120	Leesburg	VA	20176	703–858–8656	703–858–8670
Integris Baptist Medical Center.	3433 NW 56th Street, Suite 805.		Oklahoma City	OK	73112	405–949–3648	
Integris Health	600 S. Monroe Street		Enid	OK	73701	580–548–1111	580–548–1487
Integris Southwest Medical Center.	4401 South Western Avenue.		Oklahoma City	OK	73109	405–636–7574	405–231–0559
Intermountain Medical Center.	PO Box 577000		Murray	UT	84157–7000	801–507–2958	801–507–2996
Iowa Lutheran Hospital	700 E. University Avenue		Des Moines	IA	50316	515–263–5813	515–263–5415
Iowa Methodist Medical Center.	700 E. University Avenue		Des Moines	IA	50316	515–263–5813	515–263–5415
Iredell Memorial Hospital	557 Brookdale Drive		Statesville	NC	28687	704–878–4691	704–878–4632
Iroquois Memorial Hospital	200 Fairman Avenue		Watseka	IL	60970	815–432–7720	
Irvine Regional Hospital and Medical Center.	16200 Sand Canyon Avenue.		Irvine	CA	92618–3701	949–753–2036	949–753–2072
Jackson Hospital and Clinic	1725 Pine Street		Montgomery	AL	36106	334–293–8881	334–293–8899
Jackson Madison General Hospital.	708 West Forrest Avenue		Jackson	TN	38301	731–541–6326	731–425–6749
Jackson Memorial Hospital	1611 N.W. 12th Avenue		Miami	FL	33136	305–585–5084	305–585–2551
Jamaica Hospital Medical Center.	8900 VanWyck Expressway.		Jamaica	NY	11418	718 206–6191	718 206–7148

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Jane Phillips Memorial Medical Center.	3500 Frank Phillips Boulevard.		Bartlesville	OK	74006	918–331–1101	918–331–1156
Jeanes Hospital	7600 Central Avenue		Philadelphia	PA	19111	215–728–2378	
Jeff Anderson Regional Medical Center.	2124 14th Street		Meridian	MS	39301	601–553–6611	
Jefferson Memorial Hospital	PO Box 350		Crystal City	MO	63019	636–933–5412	636–933–5717
Jefferson Regional Medical Center.	1600 West 40th Avenue		Pine Bluff	AR	71603	870–541–4012	
Jefferson Regional Medical Center.	PO Box 18119 565 Coal Valley Road.		Pittsburgh	PA	15236–0119	412–469–7205	412–469–7689
Jersey City Medical Center	355 Grand Street		Neptune	NJ	07307	201–915–2206	201–915–2113
Jersey Shore University Medical Center.	1945 State Route 33		Neptune	NJ	07753	732–776–2956	732–776–4324
Jewish Hospital	4777 East Galbraith Road		Cincinnati	OH	45236	513–686–3188	513–686–4454
Jewish Hospital	200 Abraham Flexner Way		Louisville	KY	40202	502–587–4847	502–560–8570
JFK Medical Center	5631 Glencrest Boulevard		Tampa	FL	33625–1008	813–265–0997	813–265–1244
John C. Lincoln Hospital—Deer Valley.	19829 N. 27th Ave.		Phoenix	AZ	85027–4002	602–870–6060 x3202	
John C. Lincoln Hospital—North Mountain.	250 E. Dunlap Avenue		Phoenix	AZ	85020–2871	602–870–6060 x3202	
John F. Kennedy Memorial Hospital.	47–111 Monroe Street		Indio	CA	92201	760–775–8086	760–775–8454
John Muir Medical Center—Concord Campus.	2540 East Street		Concord	CA	94520	925–674–2466	
John Muir—Walnut Creek	1601 Ygnacio Valley Road		Walnut Creek	CA	94550	925–941–7951	925–941–7961
Johns Hopkins Bayview Medical Center.	4940 Eastern Avenue		Baltimore	MD	21224	410–550–3557	410–550–3384
Johns Hopkins Hospital	600 N. Wolfe Street		Baltimore	MD	21287	410–502–0396	410–614–4243
Johnson City Medical Center Hosp.	400 N State of Franklin		Johnson City	TN	37604	423–431–5690	
Jordan Valley Hospital	3580 W. 9000 S		West Jordan	UT	84088	801–562–3188	
Kadlec Medical Center	888 Swift Boulevard		Richland	WA	99352	509–942–2149	509–942–2750
Kaiser Foundation Hospital	1526 Edgemont Street		Los Angeles	CA	90027	323–783–6623	323 783 7819
Kaiser Foundation Hospital	6600 Bruceville Road		Sacramento	CA	95823	916–688–2287	916–688–6684
Kaiser Permanente—Moanalua Medical Center.	3288 Moanalua Road		Honolulu	HI	96819	808–432–0000	
Kaiser Permanente Medical Center—Santa Clara.	710 Lawrence Expressway		Santa Clara	CA	95051	408–851–3749	408–851–3862
Kaiser Permanente Medical Center Health Sciences Library.	9400 E. Rosecrans Avenue.		Bellflower	CA	90706	562–461–5679	562–461–4487
Kaiser Permanente Walnut Creek.	4647 Zion Avenue		Bellflower	CA	92120	619–528–3851	619–528–7141
Kaiser Sunnyside Medical Center.	10180 SE Sunnyside Road		Clackamas	OR	97015	503–571–6522	503–571–6560
Kansas Heart Hospital	3601 N Webb Road		Wichita	KS	67226	316–630–5369	316–630–5388
Kansas Heart Hospital	3601 N Webb Road		Wichita	KS	67226	316–630–5369	
Kansas University Hospital Authority.	3901 Rainbow Boulevard		Kansas City	KS	66160	913–588–9731	913–588–9773
Kapi'olani Medical Center Pali Momi.	98–1079 Moanalua Road		Aiea	HI	96701	808–485–4374	808–485–4400
Kaweah Delta Hospital District.	Kaweah Delta Hospital District.	400 W. Mineral King Avenue.	Visalia	CA	93291	559–624–5524	559–635–4065
Kershaw County Medical Center.	1315 Roberts Street		Camden	SC	29020	803–713–6887	803–713–6324
Kettering Medical Center	3535 Southern Boulevard		Kettering	OH	45429	937–298–3399 x57407	937–395–8647
Kingman Regional Medical Center.	3269 Stockton Hill Road		Kingman	AZ	86401	928–757–0619	928–692–1418
Kings Daughters Hospital	1901 Southwest H.K. Dodgen Loop.		Temple	TX	76502	254–742–2111	254–742–9205
Kings Daughters Medical Center.	2201 Lexington Avenue		Ashland	KY	41101	606–326–6072	606–327–5107
Kingwood Medical Center	22999 Highway 59 N		Kingwood	TX	77339	281–348–8361	281–348–8390
Knox Community Hospital	1330 Coshocton Road		Mount Vernon	OH	43050	740–393–9058	740–399–3113
Kootenai Medical Center	2003 Lincoln Way		Coeur d' Alene	ID	83814	208–666–2189	208–666–2596
Kuakini Medical Center	347 North Kuakini Street	Cardiac Cath Lab	Honolulu	HI	96817	808–547–9602	808–547–9604
Labette Health	1920 S. US Highway 59 PO BOX 956.		Parson	KS	67357	620–820–5230	
Lafayette General Medical Center.	1214 Coolidge Avenue		Lafayette	LA	70505	337–289–8674	337–289–7169
LaGrange Memorial Hospital.	120 North Oak Street		Hinsdale	IL	60521	630–856–6164	630–856–6129
Lahey Clinic	41 Mall Road		Burlington	MA	01805	781–744–1083	781–744–5577
Lake Charles Memorial Hospital.	1701 Oak Park Boulevard		Lake Charles	LA	70601	337–494–2972	337–430–6954
Lake Pointe Medical Center	6800 Scenic Drive		Rowlett	TX	75088	972–348–8773 X1711	972–463–7456
Lake Regional Health System.	54 Hospital Drive		Osage Beach	MO	65065	573–348–8773 or 573–348–8225	573–348–8266
Lakeland Hospital	1234 Napier Avenue		Saint Joseph	MI	49085–2112	616–982–4851	616–983–8232
Lakeland Regional Medical Center.	1324 Lakeland Hills Boulevard.		Lakeland	FL	33804	863–687–1100 x3318	863–413–5904

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Lakeside Hospital	6901 N. 72nd Street Suite 3300.		Omaha	NE	68122	402–572–2689	402–572–2371
Lakeview Regional Medical Center.	95 East Fairway Drive		Covington	LA	70433–7500	985–867–4080	985–867–4081
Lakeway Regional Hospital	726 McFarland Street		Morristown	TN	37814	423–522–6024	423–587–8548
Lakewood Hospital	14519 Detroit Avenue		Lakewood	OH	44107	216–227–2422	
Lakewood Ranch Medical Center.	8330 Lakewood Ranch Boulevard.		Bradenton	FL	34202	941–782–2273	941–782–2556
Lakewood Regional Medical Center.	3700 East South Street		Lakewood	CA	90712	562–272–6456	
Lancaster Community Hosp	43830 North 10th Street West.		Lancaster	CA	93534	661–940–1416	661–940–1483
Lancaster General Hospital	555 N. Duke Street PO Box 3555.		Lancaster	PA	17604–3555	717–544–4799	
Lancaster Regional Medical Center.	250 College Avenue		Lancaster	PA	17604	717–291–8232	717–291–8397
Lane Regional Medical Center.	6300 Main Street		Zachary	LA	70791	225–658–4504	
Lankenau Hospital	Suite 557 Lankenau MOB East.	100 Lancaster Avenue.	Wynnewood	PA	19096	610–526–8661	
Laredo Medical Center	1720 Bustamante Street		Laredo	TX	78044	956–796–3309	
Largo Medical Center	201 14th Street SW		Largo	FL	33770	727–588–5560	727–588–5906
Las Colinas Medical Center	6800 North MacArthur Boulevard.		Irving	TX	75039	972–969–2392	469–484–1411
Las Palmas Medical Center	1801 N. Oregon Street		El Paso	TX	79902	915–521–1478	
Lawrence & Memorial Hospital.	365 Montauk Avenue		New London	CT	06375	860–442–0711 x2699	860–442–7203
Lawrence Hospital	55 Palmer Avenue		Broxville	NY	10708–3491	914–787–3298	
Lee Memorial Health System—Cape Coral Hospital.	276 Cleveland Avenue		Fort Myers	FL	33901	239–573–5548	239–573–5542
Lee Memorial Health System—Health Park Med Center.	276 Cleveland Avenue		Fort Myers	FL	33901	239–573–5548	239–573–5542
Lee's Summit Medical Center.	2100 SE Blue Parkway		Lee's Summit	MO	64063	816–282–5582	816–282–5581
Leesburg Regional Medical Center.	600 East Dixie Avenue		Leesburg	FL	34748	352–323–5957	
Legacy Emanuel Hospital	1919 NW Lovejoy Street		Portland	OR	97209	503–415–5518	503–415–5317
Legacy Good Samaritan Hospital.	1919 NW Lovejoy Street		Portland	OR	97209	503–415–5518	503–415–5317
Legacy Meridian Park Hospital.	19300 SW 65th Avenue		Tualatin	OR	97062	503–692–1212	
Legacy Salmon Creek Hospital.	1919 NW Lovejoy Street		Portland	OR	97209	503–415–5518	
Lehigh Regional Medical Center.	1500 Lee Boulevard		Lehigh Acres	FL	33963	239–368–4470	239–368–4470
Lehigh Valley Hospital	1200 S. Cedar Crest Boulevard.	Jaindl Pavilion 1st Floor.	Allentown	PA	18103	610–402–0601	610–402–8613
Lehigh Valley Hospital—Muhlenberg.	2545 Schoenersville Road	Invasive Cardiology 3rd Floor.	Bethlehem	PA	18017–7330	610–402–0601	
Lenox Hill Heart and Vascular Institute of New York.	100 East 77th Street		New York	NY	10021	212–434–6984	
Lewis Gale Medical Center	1900 Electric Road		Salem	VA	24153	540–776–4939	540–776–4924
Lexington Medical Center	2720 Sunset Boulevard		West Columbia	SC	29169	803–791–2105	803–791–2660
Licking Memorial Hospital	1320 W. Main Street		Newark	OH	43055	740–348–4186	
Lima Memorial Hospital	1001 Bellefontaine Avenue		Lima	OH	45804	419–998–4650	419–226–5133
Lincoln Park Hospital	550 W. Webster Avenue		Chicago	IL	60614	773–883–3672	773–883–3821
Little Company of Mary Hospital.	4101 Torrance Boulevard		Torrance	CA	90503	310–303–5514	806–313–5514
Little Company of Mary Hospital.	2800 W. 95th Street		Evergreen Park	IL	60805	708–229–5593	
Logan General Hospital, LLC.	20 Hospital Drive		Logan	WV	25601	304–831–1870	304–831–1840
Loma Linda University Medical Center.	11234 Anderson Street Room 2431.		Loma Linda	CA	92354	909–558–4344	909–558–4249
Long Beach Memorial Medical Center.	2801 Atlantic Avenue		Long Beach	CA	90806	562–933–3739	562–933–3328
Long Island College Hospital.	339 Hicks Street		Brooklyn	NY	11201	718–780–2395	
Long Island Jewish Medical Center.	270–05 76th Avenue		New Hyde Park	NY	11040	718–470–4276	718–347–0753
Longmont United Hospital	1950 Moutain View Avenue.		Longmont	CO	80501	303–651–5065	
Longview Regional Medical Center.	PO Box 14000		Longview	TX	75607	903–232–3695	
Los Alamitos Medical Center.	3751 Katella Avenue		Los Alamitos	CA	90720	562–799–3193	
Los Robles Hospital & Medical Center.	215 W. Janss Road		Thousand Oaks	CA	91360–1899	805–370–4585	805–267–8914
Louisiana Medical Center and Heart Hospital.	64030 Louisiana Highway 434.		Lacombe	LA	70445	985–690–7522	985–690–7530

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Lourdes Hospital	1530 Lone Oak Road		Paducah	KY	42003	270–444–2105	270–444–2886
Lovelace Medical Center	601 Dr. Martin Luther King, Jr. Ave NE.		Albuquerque	NM	87106	505–727–8198	
Lowell General Hospital	295 Varnum Avenue		Lowell	MA	01854	978–937–6226	978–937–6913
Lower Bucks Hospital	501 Bath Road		Bristol	PA	19007	215–785–9447	215–785–9120
Lower Keys Medical Center	5900 College Road		Key West	FL	33040	305–294–5531 ext 3382	
LSUHSC—Cath Lab	1501 Kings Highway		Shreveport	LA	71130	318–675–7906	318–675–7913
Lubbock Heart Hospital	4810 N. Loop 289		Lubbock	LA	79416	806–472–5307	806–472–3894
Luther Hospital	1221 Whipple Street		Eau Claire	WI	54703	715–838–3788	
Lutheran Hospital of Indiana.	7950 W. Jefferson Boulevard.		Fort Wayne	IN	46804	260–435–7480	260–435–7632
Lutheran Medical Center	150 55th Street		Brooklyn	NY	11220	718–630–8396	
Lynchburg General Hospital	1901 Tate Springs Road		Lynchburg	VA	24501–1167	434–947–7173	434–947–4601
MacNeal Hospital	3249 S. Oak Park Avenue		Berwyn	IL	60402	708–783–3360	708–783–0052
Magnolia Regional Health Center.	611 Alcorn Drive		Corinth	MS	38834	662–293–1359	
Maimonides Medical Center Division of Cardiology.	Division of Cardiology	4802 10th Avenue.	Brooklyn	NY	11219	718–283–7094	718–635–7388
Maine Medical Center	22 Bramhall Street		Portland	ME	04102	207–662–2661	207–662–6210
Manatee Memorial Hospital	206 Second Street East		Bradenton	FL	34208	941–745–7572	941–745–6891
Marian Medical Center	1400 East Church Street		Santa Maria	CA	93454	805–739–3746	
Maricopa Integrated Health System.	2601 E. Roosevelt Street		Phoenix	AZ	85008	602–344–5722	602–344–1364
Marin General Hospital	250 Bon Air Road		Greenbrae	CA	94904	415–925–7797	415–925–7626
Marion General Hospital	441 N. Wabash Avenue		Marion	IN	46952	765–662–4874	765–662–4548
Marion General Hospital	1000 McKinley Park Drive		Marion	OH	43302–6397	740–375–6000	740–375–6017
Marquette General Hospital System.	580 W. College Avenue		Marquette	MI	49855	906–225–3536	
Martha Jefferson Hospital	459 Locust Avenue		Charlottesville	VA	22902	434–982–8472	
Martin Memorial Medical Center.	PO Box 9010		Stuart	FL	34995	772–221–2094	772–419–2104
Mary Black Hospital	1700 Skylyn Drive		Spatanburg	SC	29307	864–573–3384	864–573–3274
Mary Greeley Medical Center.	1111 Duff Avenue		Ames	IA	50010	515–239–6980	
Mary Hitchcock Memorial Hospital.	One Medical Center Drive		Lebanon	NH	03756	603–650–5704	603–650–0523
Mary Washington Hospital	1001 Sam Perry Boulevard		Fredericksburg	VA	22401	540–741–4140	540–741–2909
Marymount Medical	310 East 9th Street		London	KY	40741	606–877–6124	606–877–3834
Massachusetts General Hospital.	55 Fruit Street		Boston	MA	02114	617–643–3691	617–726–7519
Maury Regional Hospital	1224 Trotwood Avenue		Columbia	TN	38401	931–381–1111 x1663	
Mayo Clinic Arizona	5777 E. Mayo Boulevard		Phoenix	AZ	85054	480–342–3005	480–342–2345
Mayo Clinic—St. Mary's Hospital.	200 First Street SW		Rochester	MN	55905	507–284–2111	
McAlester Regional Health Center.	1 Clark Bass Boulevard		McAlester	OK	74501	918–421–8087	
McAllen Medical Center	301 W. Expressway 83		McAllen	TX	78503	956–632–4019	
MCG Health Inc.	1120 15th Street BBR–8521.		Augusta	GA	30912	706–721–1118	706–721–0347
McKay-Dee Hospital Center	4401 Harrison Boulevard		Ogden	UT	84405	801–387–3000	
McKee Medical Center	2000 Boise Avenue		Loveland	CO	80538	970–635–4118	
McLeod Regional Medical Center.	555 E. Chaves Street		Florence	SC	29501	843–777–2101	843–777–5075
Mease Countryside Hospital	3231 Mccullen Booth Road		Safety Harbor	FL	34695	727–461–8274	
Mease Dunedin Hospital	207 Jeffords Street MS 142.		Clearwater	FL	33756	727–461–8274	727–461–8651
Med Central Mansfield	335 Glessner Avenue		Mansfield	OH	44903	419–526–8450	419–526–8246
Medcenter One	300 N. 7th Street		Bismarck	ND	58501	701–323–6529	
Medical Center at Bowling Green.	250 Park Street		Bowling Green	KY	42101	270–796–2464	270–796–2462
Medical Center Hospital	500 W. 4th Street		Odessa	TX	79760	432–640–2262	432–640–2282
Medical Center of Aurora	1501 S. Potomac Street		Aurora	CO	80012	303–873–5868	303–873–5747
Medical Center of Central Georgia.	777 Hemlock Street HB 53		Macon	GA	31208	478–633–1977	478–633–4349
Medical Center of Louisiana at New Orleans.	1541 Tulane Avenue Room #203 Butterworth Building.		New Orleans	LA	70112	504–903–0857	504–903–2270
Medical Center of McKinney.	4500 Medical Center Drive		McKinney	TX	75069	972–540–4332	972–540–4525
Medical Center of Mesquite	1011 N. Galloway Avenue		Mesquite	TX	75149	214–319–2829	214–320–7047
Medical Center of Plano	3901 W. 15th Street		Plano	TX	75075–7738	972–519–1341	972–519–1214
Medical Center of the Rockies.	2500 Rocky Mountain Avenue.		Loveland	CO	80538	970–624–1705	
Memorial Health Sysytem	1400 E. Boulder Street		Colorado Springs	CO	80909–5599	719–365–5313	719–365–5730
Medical City Dallas Hospital	7777 Forest Lane		Dallas	TX	75230	972–566–5573	972–566–8046
Medical University of South Carolina.	326 Calhoun Street Suite 239.		Charleston	SC	29401	843–792–6401	843–792–0072
Memorial Health System	1400 E. Boulder Street		Colorado Springs	CO	80909–5599	719–365–5313	719–365–5730
Memorial Health University Medical Center.	Cardiac Cath Lab Memorial Health University Medical Center.	4700 Waters Avenue.	Savannah	GA	31404	912–350–7233	912–350–7692

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Memorial Hermann Hospital	6411 Fannin Street		Houston	TX	77030	713–704–0173	
Memorial Hermann HVI South West.	7787 Southwest Freeway		Houston	TX	77074	713–778–2227	713–778–2290
Memorial Hermann Memorial City Hospital.	921 Gessner Road		Houston	TX	77024	713–242–3968	713–242–3539
Memorial Hermann Northeast.	18951 Memorial North		Humble	TX	77338	281–540–7974	281–540–6411
Memorial Hermann Northwest Hospital.	1635 North Loop West		Houston	TX	77008	713–867–4587	
Memorial Hermann The Woodlands Hospital.	9250 Pinecroft Drive		Spring	TX	77380	281–364–4185	281–364–4186
Memorial Hospital	2525 Desales Avenue		Chattanooga	TN	37404–1102	423–495–6245	423–495–4122
Memorial Hospital at Gulfport.	4500 13th Street	PO Box 1810	Gulfport	MS	39502	228–575–2482	228–575–2469
Memorial Hospital Carbondale.	405 W. Jackson Street		Carbondale	IL	65902	618–549–0721 x65472	618–529–0437
Memorial Hospital Miramar	1901 SW 172 Avenue		Miramar	FL	33029	954–538–4650	
Memorial Hospital of Martinsville.	320 Hospital Drive		Martinsville	VA	24112	276–666–7799	
Memorial Hospital of Rhode Island Brown University.	111 Brewster Street		Pawtucket	RI	02860	401–729–2642	
Memorial Hospital of South Bend.	615 N. Michigan Street		South Bend	IN	46601–1033	574–647–3593	574–647–6691
Memorial Hospital of Tampa.	2901 W. Swann Avenue		Tampa	FL	33609	813–0873–6400 x5305	813–342–1515
Memorial Hospital Pembroke/ South Broward Hospital.	7800 Sheridan Street		Pembroke Pines	FL	33024	954–963–8000	
Memorial Hospital West/ South Broward Hospital District.	703 North Flamingo Road		Pembroke Pines	FL	33028	954–430–6880 x7510	
Memorial Hospital—Jacksonville.	3625 University Boulevard South.		Jacksonville	FL	32215	904–399–6019	904–399–6381
Memorial Hospitals Association.	1700 Coffee Road		Modesto	CA	95355	209–526–4500 ext. 6084	209–572–7017
Memorial Medical Center	701 N. First Street		Springfield	IL	62781	217–757–4263	217–788–5526
Memorial Medical Center	2450 S. Telshor Boulevard		Las Cruces	NM	88011	505–556–5861	505–521–5076
Memorial Medical Center	1086 Franklin Street		Johnstown	PA	15905–4398	814–534–3459	814–534–3467
Memorial Regional Hospital/ South Broward Hospital.	3501 Johnson Street		Hollywood	FL	33021	954–987–2020 x1025	954–986–6949
Memphis Hospital (Germantown Campus).	1265 Union Avenue		Memphis	TN	38104–3499	901–516–9087	
Memphis Hospital (North Campus).	1265 Union Avenue		Memphis	TN	38104–3499	901–516–9087	901–516–2682
Memphis Hospital (University Campus).	1265 Union Avenue		Memphis	TN	38104–3499	901–516–9087	
Menifee Valley Medical Center.	28400 McCell Boulevard		Sun City	CA	92585	951–672–7042	951–672–7055
Menorah Medical Center	5721 West 119th Street		Overland Park	KS	66209	913–498–6033	913–498–6106
Mercy Fitzgerald Hospital	1500 Lansdowne Avenue		Darby	PA	19023	610–237–4328	610–237–4264
Mercy General Health Partners.	1500 E. Sherman Boulevard.		Muskegon	MI	49444	231–672–4606	231–672–3965
Mercy General Hospital—Sacramento.	3939 J Street	Suite 215	Sacramento	CA	95819	916–453–4231	916–453–4587
Mercy Gilbert Medical Center.	3555 South Val Vista Drive	Attn.: Cardiac Cath Lab.	Gilbert	AZ	85296	480–728–7050	480–728–9645
Mercy Health System of Northwestern Arkansas.	1200 West Walnut Street		Rogers	AR	72756	479–986–3422	479–619–3237
Mercy Hospital	2925 Chicago Avenue		Minneapolis	MN	55407	763–458–3245	763–322–8738
Mercy Hospital—Scranton	746 Jefferson Avenue		Scranton	PA	18501	570–348–7885	570–348–2147
Mercy Hospital & Medical Center.	2525 South Michigan Avenue.		Chicago	IL	60616	312–567–7938	312–567–6587
Mercy Hospital Attn.: Accounts Payable.	3663 South Miami Avenue		Miami	FL	33133	305–860–5271	305–860–5163
Mercy Hospital of Buffalo	565 Abbott Road		Buffalo	NY	14220	716–828–2824	716–828–2714
Mercy Hospital Attn: A/P	271 Carew Street PO Box 9012.		Springfield	MA	01102	413–748–9621	413–748–9634
Mercy Iowa City	500 East Market Street		Iowa City	IA	52245	319–339–3678	
Mercy Medical Center	2700 Steward Parkway		Roseburg	OR	97470	541–677–2471	541–677–4416
Mercy Medical Center	801 5th Street		Sioux City	IA	51101	712–279–2348	
Mercy Medical Center	1111 6th Avenue		Des Moines	IA	51101	712–279–2348	
Mercy Medical Center	1320 Mercy Drive	Cardiology Management and Support 3C.	Canton	OH	44708	330–489–1000 x1637	
Mercy Medical Center	301 St. Paul Place		Baltimore	MD	21202	410–951–7947	
Mercy Medical Center	500 S. Oakwood Road		Oshkosh	WI	54904	920–730–2621	
Mercy Medical Center	701 10th Street SE		Cedar Rapids	IA	52403	319–533–0060	319–398–6336
Mercy Medical Center	1000 North Village Ave		Rockville Centre	NY	11571	516–705–2058	516–705–2774
Mercy Medical Center Merced.	301 E. 13th Street		Merced	CA	95340	209–385–7814	209–385–7816
Mercy Medical Center Redding.	2175 Rosaline Avenue;	PO Box 496009	Redding	CA	96049–6009	530–247–3474	530–242–5212
Mercy Medical Center—North Iowa.	1000 4th Street SW		Mason City	IA	50401	641–422–5177	641–422–5179

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Mercy Regional Health Center.	1823 College Avenue		Manhattah	KS	67218	785–776–2889	
Mercy Regional Medical Center.	1010 Three Springs Boulevard.		Durango	CO	81301	970–764–2285	970–764–2299
Mercy San Juan Hospital	3941 J Street	c/o Mercy General Hospital Administration.	Sacramento	CA	95819	916–453–4231	916–453–4587
MeritCare Hospital	MeritCare Hospital/Heart Services Data/Research.		Fargo	ND	58122	701–234–7242	701–234–7404
Meriter Hospital	202 South Park Street	10 Tower—Heart Center.	Madison	WI	53715	608–417–5875	608–417–6198
Mesa General Hospital	515 N. Mesa Drive		Mesa	AZ	85201	480–827–2448	480–827–2495
Methodist Health System	PO Box 655999		Dallas	TX	75203	214–947–8181	
Methodist Hospital	7700 Floyd Curl Drive		San Antonio	TX	78229	210–575–6808	
Methodist Hospital	6500 Excelsior Boulevard 2nd Floor HVC.		St. Louis Park	MN	55426	952–993–2362	952–993–6879
Methodist Hospital of South CA.	300 W Huntington Drive		Arcadia	CA	91007–3402	626–898–8670	626–821–6982
Methodist Hospital Southlake Campus.	8701 Broadway		Merrillville	IN	46410–7035	219–738–3555	219–738–3431
Methodist Medical Center	280 Fort Sanders Boulevard Building 4, Suite 218.		Knoxville	TN	37922	865–531–5361	865–531–5036
Methodist Medical Center of Illinois.	221 NE Glen Oak Avenue		Peoria	IL	61636	309–672–4133	309–672–4116
Methodist Speciality and Transplant Hospital.	7700 Floyd Curl Drive		San Antonio	TX	78229		
Methodist Sugar Land Hospital.	16655 Southwest Freeway		Sugar Land	TX	77479	281–274–8325	281–274–8335
Methodist Willowbrook Hospital.	18220 Tomball Parkway		Houston	TX	77070	281–477–1044	
Metro Health Hospital	5900 Byron Center Road		Wyoming	MI	49519	616–252–7415	616–252–0417
MetroHealth Medical Center	2500 MetroHealth Drive		Cleveland	OH	44109	216–778–4793	216–778–8662
Metroplex Hospital	2201 S. Clear Creek Road		Killeen	TN	76549	254–519–8447	
MetroWest Medical Center	115 Lincoln Street	Cardiac Cath Lab	Framingham	MA	01702–6327	508–383–1338	508–383–1458
Miami Valley Hospital	One Wyoming Street		Dayton	OH	45409	937–208–6638	937–208–6685
Middletown Regional Hospital.	One Medical Center		Franklin	OH	45005	513–420–5755 x6452	513–420–5002
Midland Memorial Hospital	2200 W. Illinois Avenue c/o Heart Institute.		Midland	TX	79701	432–685–6966	
Midlands Community Hospital.	6901 N. 72nd Street		Omaha	NE	68122	402–572–2689	402–572–2371
MidMichigan Medical Center—Midland.	4005 Orchard Drive		Midland	MI	48670	989–837–9044	989–837–9032
Midwest Regional Medical Center.	2825 Parklawn Drive		Midwest City	OK	73110	405–610–8069	
Milford Regional Medical Center.	14 Prospect Street		Milford	MA	01568	508–422–2463	508–487–9328
Millard Fillmore Hospital	100 High Street		Buffalo	NY	14203	716–859–1080	716–859–3765
Mills-Peninsula Hospital	1783 Elcamino Real		Burlingame	CA	94010	650–696–5937	650–696–5460
Mission Hospital Regional Medical Center.	27700 Medical Center Road.		Mission Viejo	CA	92691–6426	949–364–1400 x2048	949–365–2320
Mission Hospitals, Inc.	509 Biltmore Avenue		Asheville	NC	28801–4690	828–213–7037	828–213–7296
Mission Regional Medical Center.	900 S. Bryan Road		Mission	TX	78572	956–323–1904	
Mississippi Baptist Medical Center.	1225 N State Street		Jackson	MS	39202–2097	601–968–1011	601–968–1142
Missouri Baptist Medical Center.	3015 N. Ballas Road	3105 North Ballas Road.	Saint Louis	MO	63131–2374	314–996–5693	314–432–2245
Moberly Regional Medical Center.	1515 Union Avenue		Moberly	MO	65270	660–269–2949	660–269–2948
Mobile Infirmary Medical Center.	PO Box 2144		Mobile	AL	36652	251–435–2540	251–435–7278
Monongalia Genera; Hospital.	1200 JD Anderson Drive		Morgantown	WV	26505	304–285–5173	304–285–5109
Montefiore Medical Center	111 East 210th Street		Bronx	NY	10467–2490	718–920–7389	718–920–6798
Montgomery General Hospital.	18101 Prince Philip Drive		Olney	MD	20832	301–774–8952	301–570–7866
Morris Hospital	150 West High Street		Morris	IL	60450	815–942–2932	815–942–9538
Morristown Memorial Hospital.	100 Madison Avenue		Morristown	NJ	07962	973–971–8848	973–290–7337
Morton Plant Hospital	207 Jeffords Street		Clearwater	FL	33756	727–461–8274	727–461–8651
Morton Plant North Bay Hospital.	6600 Madison Street		New Port Richey	FL	34652	727–461–8274	
Moses Cone Health System	1200 N. Elm Street		Greensboro	NC	27401	336–832–2851	336–832–2851
Mother Frances Hospital	800 E.Dawson Street		Tyler	TX	75701	903–531–4309	903–525–1589
Mount Auburn Hospital	330 Mount Auburn Street	South 2—Administration.	Cambridge	MA	02138	617–441–1625	617–499–5132
Mount Carmel East	6150 East Broad Street	Office EB 148	Columbus	OH	42313	614–546–4786	614–546–4798
Mount Carmel St. Ann's Hospital.	6150 East Broad Street	Office EB 148	Columbus	OH	42313	614–546–4786	614–546–4798
Mount Carmel West	6150 East Broad Street	Office EB 148	Columbus	OH	42313	614–546–4786	614–546–4798
Mount Clemens Regional Medical Center.	1000 Harrington Street		Mount Clemens	MI	48043–2992	586–493–8088	586–493–8835

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Mount Sinai Medical Center	4300 Alton Road		Miami Beach	FL	33140	305–535–7950	305–674–2556
Mountainview Hospital	3100 N. Tenaya Way		Las Vegas	NV	89128	702–255–5102	702–255–5029
Munroe Regional Medical Center.	1500 SW 1st Avenue PO Box 6000.		Ocala	FL	34478	352.351.7200 ext 6478	352.671.2034
Munson Medical Center	1105 Sixth Street		Traverse City	MI	49684–2386	231–935–7633	231–315–6524
Muskogee Regional Medical Center.	300 Rockefeller Drive		Muskogee	OK	74401	918–684–2357	918–781–6308
Nacogdoches Medical Center.	4920 NE Stallings Drive		Nacogdoches	TX	75965	936–568–3407	
Naples Community Hospital	350 7th Street South		Naples	FL	34102	239–436–5226	
Natchez Regional Medical Center.	54 Sgt. Prentiss Drive		Natchez	MS	39120	601–443–2691	
NEA Baptist Memorial Hospital.	3024 Stadium Boulevard		Jonesboro	AR	72401	870–972–7079	
Nebraska Heart Hospital	7500 South 91st Street		Lincoln	NE	68526	402–328–3047	402–328–3035
Nebraska Methodist Hospital.	8303 Dodge Street		Omaha	NE	68114	402–354–4733	402–354–8790
New Hanover Regional Medical Center.	2131 S. 17th Street		Wilmington	NC	28402	910–342–3285	910–342–3820
New Milford Hospital	21 Elm Street		New Milford	CT	06776	860–210–5065	860–350–7714
New York Community Hospital.	2525 Kings Highway		Brooklyn	NY	11229	718–692–8745	718–692–8456
New York Hospital Medical Center of Queens Health Education Library.	56–45 Main Street EO Lab 3rd Floor.		Flushing	NY	11355	718–661–7400	
New York Methodist Hospital.	506 6th Street Brooklyn		New York City	NY	11215	718–780–3464	718–780–7763
New York Presbyterian Hospital.	6220West 168th Street	PH–2	New York City	NY	10032	212–305–1788	212–305–1708
Newark Beth Israel Medical Center.	201 Lyons Avenue at Osborne Terrace.		Newark	NJ	07112	973 926 7283	973 926 6526
Nicholas H. Noyes Memorial Hospital.	111 Clara Barton Street		Dansville	NY	14437	585–335–4349	585–335–5881
NIX Healthcare System	414 Navarro Street		San Antonio	TX	78205	210–579–3221	
Norman Regional Health System.	PO Box 1308		Norman	OK	73070–1308	405–307–1064	405–307–1168
North Austin Medical Center.	12221 MoPac Expressway North.		Austin	TX	78758	512–901–1327	512–901–1969
North Bay Medical Center	1200 B. Gale Wilson Boulevard.		Fairfield	CA	94533	707–429–6706	707–429–6862
North Carolina Baptist Hospital.	Medical Center Boulevard		Winston-Salem	NC	27157	336–716–5861	
North Central Baptist Hospital.	520 Madison Oak Drive		San Antonio	TX	78258	210–297–1264	210–297–0926
North Colorado Medical Center.	1801 16th Street		Greeley	CO	80631	970–350–6167	970–350–6164
North Cypress Medical Center.	21214 Northwest Freeway		Cypress	TX	77429	832–912–3500	
North Florida Regional Medical Center.	6500 Newberry Road		Gainesville	FL	32605	352–333–4925	352–333–4295
North Hills Hospital	4401 Booth Calloway Road		North Richland Hills.	TX	76180	817–255–1894	817–255–1888
North Kansas City Hospital	2800 Clay Edward Drive		North Kansas City	MO	64116	816–691–5036	816–346–7672
North Memorial Medical Center.	3300 Oakdale Avenue, N		Robbinsdale	MN	55422	763–520–5478	
North Mississippi Medical Center.	830 S. Gloster Street		Tupelo	MS	38801	662–377–4667	662–377–2733
North Oaks Medical Center	15790 Paul Vega MD Drive.		Hammond	LA	70403	985–230–6836	985–230–6438
North Ridge Medical Center	5757 N. Dixie Highway		Fort Lauderdale	FL	33334	954–776–6000 x2137	954–202–4876
North Shore Medical Center—Salem Hospital.	81 Highland Avenue	Davenport 5	Salem	MA	01970	978–354–2506	978–825–6493
North Shore University Hospital.	300 Community Drive		Manhasset	NY	11030	516–562–1463	516–562–3675
North Suburban Medical Center.	9191 Grant Street		Denver	CO	80229	303–450–4447	303–450–4594
North Vista Hospital	1409 E. Lake Mead Boulevard.		North Las vegas	NV	89030	702–657–5504	
Northeast Alabama Regional Medical Center.	PO Box 2208	400 East 10th Street.	Anniston	AL	36202	256–235–5499	256–231–8362
Northeast Baptist Hospital	8811Village Drive		San Antonio	TX	78217	210–297–1264	210–297–0926
Northeast Georgia Medical Center.	743 Spring Street		Gainesville	GA	30501	678–989–2818	770–538–7592
NorthEast Medical Center	920 Church Street North		Concord	NC	28025	704–783–4156	704–783–1436
Northeast Methodist Hospital.	12412 Judson Road		Live Oak	TX	78233	210–757–5868	210–757–5859
Northern Illinois Medical Center.	4201 Medical Center Drive		McHenry	IL	60050	815–759–4581	815–759–4568
Northern Michigan Regional Hospital.	416 Connable Avenue		Petoskey	MI	49770	231–487–7581	231–487–7720
Northridge Hospital Medical Center.	18300 Roscoe Avenue		Northridge	CA	91325	818–885–8500 ext. 2283	818–885–5333

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Northshore Regional Medical Center.	100 Medical Center Drive		Slidell	LA	70461	985–646–5746	985–646–5007
Northside Hospital	1000 Johnson Ferry Road		Atlanta	GA	30342	404–851–8963	
Northside Hospital	6000 49th Street, N		Pinellas Park	FL	33709	727–521–5068	727–521–5044
Northside Hospital—Forsyth	1200 Northside Forsyth Drive.		Cumming	GA	30041	770–844–3607	770–844–3503
Northwest Community Hospital.	800 W. Central Road		Arlington Heights	IL	60005	847–618–7627	
Northwest Hospital	1550 North 115th Street		Seattle	WA	98113	206–368–5760	
Northwest Hospital center	5401 Old Court Road		Randallstown	MD	21133	410–496–7126	410–521–2843
Northwest Medical Center	2801 N. State Road 7		Margate	FL	33063	954–978–4059	
Northwest Medical Center	Northwest Medical Center	6200 N. La Cholla Boulevard.	Tucson	AZ	85741	520–469–8489	520–469–8949
Northwest Medical Center—Bentonville.	3000 Medical Center Parkway.		Bentonville	AR	72712	479–553–4508	
Northwest Medical Center—Springdale.	609 West Maple Street		Springdale	AR	72764	479–757–4244	
Northwest Mississippi Regional Medical Center.	1970 Hospital Drive		Clarksdale	MS	38614	662–624–3283	662–621–5077
Northwestern Memorial Hospital.	676 N. St. Clair Street, Suite 1700.		Chicago	IL	60611	312–926–1096	312–695–6854
Norton Audubon	PO Box 35070		Louisville	KY	40232	502–629–8893	502–629–4044
Norton Hospital	PO Box 35070		Louisville	KY	40232	502–629–8893	502–629–4044
Norwalk Hospital	24 Stevens Street		Norwalk	CT	06856	203–852–2127	
NYU Medical Center	560 First Avenue		New York	NY	10016	212–263–7514	
Oak Hill Hospital	11375 Cortez Boulevard		Brooksville	FL	34613	352–597–7085	
Oakwood Hospital & Medical Center.	18101 Oakwood Boulevard Suite 124.		Dearborn	MI	48124	313–593–8581	313–436–2082
Obici Hospital	2800 Godwin Boulevard		Suffolk	VA	23434	757–934–4500	
Ocala Regional Mecical Center.	1431 SW First Avenue		Ocala	FL	34474	352–401–1484	352–401–1552
Ocean Springs Hospital	3109 Bienville Boulevard		Ocean Springs	MS	39564	228–818–1111	
Ochsner Medical Center—Baton Rouge.	17000 Medical Center Drive.		Baton Rouge	LA	70816	225–755–4934	225–755–4870
Ochsner Medical Center—West Bank.	2500 Belle Chasse Highway.		Gretna	LA	70056	504–391–5560	504–391–5530
Ochsner Medical Center—Kenner (Kenner Regional Medical Center).	180 West Esplanade Avenue.		Kenner	LA	70065	504–464–8116	504–464–8733
Ochsner Medical Foundation.	1514 Jefferson Highway		New Orleans	LA	70121	504–842–3726	504–838–8853
Oconee Regional Medical Center.	812 N. Cobb Street		Milledgeville	GA	31061	478–454–3663	
O'Connor Hospital	2105 Forest Avenue		San Jose	CA	95128	408–918–6224	
Odessa Regional Hospital	520 East Sixth Street		Odessa	TX	79760	432–582–8147	432–582–8927
Ogden Regional Medical Center.	5475 South 500 East		Ogden	UT	84403	801–479–2473	801–479–2037
Ohio State University Medical Center.	≤410 W. 10th Avenue	142 Doan Hall	Columbus	OH	43210–1228	614–293–6332	614–293–8862
Ohio Valley Medical Center	2000 Eoff Street		Wheeling	WV	26003	304–234–8146	304–234–1815
Oklahoma Heart Hospital	4050 W. Memorial Road		Oklahoma City	OK	73120	405–608–3511	405–608–1498
Oklahoma State University Medical Center.	744 W. 9th Street		Tulsa	OK	74127	918–599–5239	918–599–5444
Olathe Medical Center	20333 W. 151st Street		Olathe	KS	66061–7211	913–791–4265	913–791–3508
Opelousas General Health System.	539 E. Prudhomme Street		Opelousas	LA	70570	337–594–3912	337–407–1403
Orange Coast Memorial Medical Center.	9920 Talbert Avenue		Fountain Valley	CA	92708	714–378–7505	714–378–7161
Orange Regional Medical Center.	60 Prospect Avenue		Middletown	NY	10940	845–343–2424 ext. 4503	
Oregon Health & Science University.	3181 SW Sam Jackson Road.		Portland	OR	97239	503–494–3405	503–494–0822
Orlando Regional Medical Center.	1414 Kuhl Avenue		Orlando	FL	32806	321–841–8047	407–872–1275
Osceola Regional Medical Center.	700 W. Oak Street		Kissimmee	FL	34745	407–518–3994	
OSF Saint Anthony Medical Center.	5666 East State Street		Rockford	IL	61108	815–227–2160	
OSF Saint Joseph Medical Center.	2200 E. Washington Street		Bloomington	IL	61701	309–661–5070	
OSF Saint Francis Medical Center.	530 N.E. Glen Oak Avenue		Peoria	IL	61637	309–655–6839	309–655–7861
OU MEDICAL CENTER	700 NE 13th Street		Oklahoma City	OK	73104	405–271–4811	
Our Lady of Lourdes Medical Center.	1600 Haddon Avenue		Camden	NJ	08103	856–365–4082	
Our Lady of Lourdes Regional Medical Center.	611 Saint Landry Street PO Box 4027.		Lafayette	LA	70506	337–289–4650	
Our Lady of The Lake Regional.	5000 Hennessy Boulevard		Baton Rouge	LA	70808–4350	225–765–8691	225–765–6638
Our Lady of the Resurrection Medical Center.	5645 W. Addison Street		Chicago	IL	60634	773–794–7638	773–794–8428
Overlake Hospital Medical Center.	1035 116th Avenue NE		Bellevue	WA	98004	425–688–3722	425–283–5119

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Overland Park Regional Medical Center/Health Midwest.	10500 Quivira Road		Overland Park	KS	66215	913–541–5996	
Owensboro Medical Health System.	811 E. Parrish Avenue		Owensboro	KY	42303	270–688–1594	270–688–2683
Ozarks Medical Center	100 Kentucky Avenue		West Plains	MO	65775	417–256–1718	417–256–1785
P and S Surgical Hospital	312 Grammont Street		Monroe	LA	71201	318–998–8212	318–998–8220
Palm Beach Gardens Medical Center.	3360 Burns Road		Palm Beach Gardens.	FL	33410	561–694–7185	
Palmetto General Hospital	2001 West 68th Street		Hialeah	FL	33016	305–819–1208	305–819–1203
Palmetto Health Heart Hospital.	6 Richland Medical Park Drive.	Suite 4525	Columbia	SC	29203	803–434–2049	803–434–2058
Palomar Medical Center	555 East Valley Parkway		Escondido	CA	92025	760–739–3551	
Palos Community Hospital	12251 S. 80th Avenue	Cardiovascular Services.	Palos Heights	IL	60463–0930	708–923–5443	708–923–4448
Paoli Hospital	557 Lankenau MOB East	100 Lancaster Avenue.	Wynnewood	PA	19096	610–526–8661	
Paradise Valley Hospital	3929 E. Bell Road		Phoenix	AZ	85032	602–923–5777	602–923–5750
Paradise Valley Hospital	2400 E. Fourth Street		National City	CA	91950	619–470–4263	619–470–4162
Paris Regional Medical Center.	820 Clarksville Street		Paris	TX	75460	903–737–3874	903–737–3649
Park Plaza Hospital	1313 Hermann Drive		Houston	TX	77004	713–527–5112	
Parkland Health and Hospital Systems.	5201Harry Hines Boulevard.		Dallas	TX	75235	214–590–8966	
Parkridge Medical Center	2333 McCallie Avenue		Chattanooga	TN	37404	423–493–1798	423–493–7962
Parkview Hospital	2200 Randallia Drive		Fort Wayne	IN	46805	260–373–4640	260–373–7295
Parkview Hospital	1726 Shawano Avnue		Green Bay	WI	54303–3282	920–498–4235	
Parkview Medical Center	400 W. 16th Street		Pueblo	CO	81003	719–584–4650	719–584–4209
Parkwest Medical Center	9352 Parkwest Boulevard		Knoxville	TN	37923	865–373–1328	865–373–1322
Parma Community General Hospital.	7007 Powers Boulevard		Parma	OH	44129	440–743–2317	440–743–4058
Parrish Medical Center	951 N. Washington Avenue.		Titusville	FL	32796	321–268–6874	321–268–6369
Pasco Regional Medical Center.	13000 100 Fort King Road		Dade City	FL	33525	352–518–1020	
Peace River Regional Medical.	2500 Harbor Boulevard		Port Charlotte	FL	33952	941–766–4142	941–766–4169
Peconic Bay Medical Center.	1300 Roanoake Avenue		Riverhead	NY	11901	631–548–6871	
Peninsula Regional Medical Center.	100 East Carroll Street		Salisbury	MD	21801	410–543–7530 x3444	410–543–7134
Penn Presbyterian Medical Center.	39th & Market Streets		Philadelphia	PA	19104	215–662–9142	215–243–3254
Penn State Hershey Medical Center.	PO Box 850 H139		Hershey	PA	17033	717–531–6416	717–531–0174
Pennsylvania Hospital	800 Spruce Street		Philadelphia	PA	19107–6192	215–829–5335	
Penrose—St. Francis Health Services.	2222 North Nevada, #220		Colorado Springs	CO	80907	1–719–776–2992	1–719–776–5823
Phelps County Regional Medical Center.	1000 W. 10th Street		Rolla	MO	65401	573–458–7689	
Phoenix Baptist Hospital	2000 W. Bethany Home Road.		Phoenix	AZ	85015	602–246–5511	602–246–5929
Phoenixville Hospital	140 Nutt Road		Phoenixville	PA	19460–3906	610–983–1236	610–983–1238
Physicians Medical Center Carraway.	1600 Carraway Boulevard		Birmingham	AL	35234	205–502–6936	205–502–5563
Piedmont Hospital	95 Collier Road Suite 2075		Atlanta	GA	30309	404–605–3122	404–605–0276
Piedmont Medical Center	222 S. Herlong Avenue		Rock Hill	SC	29732	803–981–7499	
Pikesville Medical Center	911 Bypass Road		Pikesville	KY	41501	606–218–4961	606–437–3979
Pinnicle Health Invasive Cardiology.	111 South Front Street		Harrisburg	PA	17101–2099	717–782–3170	717–782–5807
Pioneer Valley Hospital	3590 West 9000 South, Suite 315.		West Jordan	UT	84088		
Pitt County Memorial Hospital.	300 Moye Boulevard		Greenville	NC	27834	252–744–5316	252–744–1317
Plantation General Hospital	401 NW 42nd Avenue		Plantation	FL	33317	954–513–6459	
Plaza Medical Center of Fort Worth.	900 Eighth Avenue		Fort Worth	TX	76104	817–347–4957	817–347–5711
Pocono Medical Center	206 East Brown Street		East Stroudsburg	PA	18301	570–420–5878	570–422–8394
Pomona Valley Hospital Med Center.	1798 N. Garey Avenue		Pomona	CA	91768	909–865–9501 x4331	909–623–6354
Pontiac Osteopathic Hospital.	50 N. Perry Street		Pontiac	MI	48342	248–338–5229	248–338–5569
Poplar Bluff Regional Medical Center.	2620 N. Westwood Boulevard.		Poplar Bluff	MO	63901	573–727–2544	573–727–2549
Port Huron Hospital	1221 Pine Grove Avenue		Port Huron	MI	48060	810–985–2631	810–985–2696
Porter Adventist Hospital	2525 S. Downing Street		Denver	CO	80210–5817	303–765–3593	303–765–3734
Porter Valparaiso Hospital Campus.	814 Laporte Avenue		Valparaiso	IN	46383	219–263–7277	219–263–7942
Portneuf Medical Center	651 Memorial Drive		Pocatello	ID	83201	208–239–2554	208–239–3741
Portsmouth Regional Hospital.	333 Borthwick Avenue		Portsmouth	NH	03801	603–433–5266	603–433–4047
Prairie Lakes Healthcare	401 9th Avenue		Watertown	SD	57201	605–882–7672	605–882–7720
Presbyterian Healthcare Services.	PO Box 26666		Albuquerque	NM	87125	505–841–1145	505–841–1382

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Presbyterian Hospital	200 Hawthorne Lane		Charlotte	NC	28233	704–384–9838	704–316–9104
Presbyterian Hospital—Denton.	3000 I–35 N		Denton	TX	76201	940–898–7225	
Presbyterian Hospital—Dallas.	Presbyterian Hospital	8200 Walnut Hill Lane.	Dallas	TX	75231	214–345–6022	214–345–6081
Presbyterian Hospital—Plano.	6200 West Parker Road		Plano	TX	75093–7914	972–981–3362	972–981–3022
Presbyterian Intercommunity Hospital.	12401 Washington Boulevard.		Whittier	CA	90602	562–698–0811 ext. 2637	562–698–1351
Presbyterian/St.Luke's Medical Center.	1719 E. 19th Avenue		Denver	CO	80218–1235	303–839–6164	303–839–6786
Prince George's Hospital Center.	3001 Hospital Drive		Cheverly	MD	20785	240–988–2272	301–618–6460
Princeton Baptist Medical Center.	Princeton BMC, Nursing Administration 701 Princeton Avenue, SW.		Birmingham	AL	35211–1399	205–783–3327	205–783–7172
Proctor Hospital	5409 N. Knoxville Avenue		Peoria	IL	61614	309–689–8641	309–689–8629
Protestant Memorial Medical Center.	4500 Memorial Drive		Belleville	IL	62226	618–257–5046	618–257–6811
Provena Covenant Medical Center.	1400 West Park Street		Urbana	IL	61801–9901	217–443–5000 x4614	
Provena Mercy Medical Center.	1325 North Highland Avenue.		Aurora	IL	60506	630–801–2796	630–801–5545
Provena Saint Joseph Medical Center.	333 North Madison Street		Joliet	IL	60435–6595	815–725–7133	815–773–7072
Provena Saint Marys Hospital.	500 West Court Street		Kankakee	IL	60901	815–937–2137	815–935–6662
Provena St. Joseph Hospital.	77 N. Airlite Street		Elgin	IL	60123	847–695–3200 x5321	847–888–3514
Providence Alaska Medical Center.	3200 Providence Drive		Anchorage	AK	99508–4662	907–261–4934	907–261–3683
Providence Everett Medical Center.	1321 Coby Avenue	PO Box 1147	Everett	WA	98206–1147	425–261–3904	425–261–3901
Providence Health Center	6901 Medical Parkway		Waco	TX	76712	254–751–4732	254–751–4584
Providence Holy Cross Medical Center.	501 South Buena Vista Street.		Burbank	CA	91505	818–847–3897	
Providence Hospital	6801 Airport Boulevard		Mobile	AL	36608	251–631–3455	251–639–2911
Providence Hospital	2435 Forest Drive		Columbia	SC	29204	803–227–7039	803–400–5039
Providence Medford Medical.	1111 Crater Lake Avenue		Medford	OR	97504	541–732–6698	541–732–6698
Providence Medical Center	8929 Parallel Parkway		Kansas City	KS	66112–1689	913–596–4614	913–596–4996
Providence Memorial Hospital.	2001 North Oregon Street		El Paso	TX	79902	915–747–2873	915–747–2873
Providence Portland Medical Center.	9205 SW Barnes Road	9205 South West. Barnes Road.	Portland	OR	97225	503–216–7184	503–216–7274
Providence Saint Joseph Medical Center.	501 South Buena Vista Street.		Burbank	CA	91505	818–847–3897	
Providence Saint Vincent Medical Center.	Regional Heart Data Services.	9205 South West Barnes Road #33.	Portland	OR	97225	503–216–7184	503–216–7274
Providence St. Peter Hospital.	413 N. Lilly Road		Olympia	WA	98506	360–493–4508	360–493–5213
Queen of the Valley Medical Center.	1000 Trancas Street		Napa	CA	94558	707–251–1390	707–251–1722
Queens Medical Center	1301 Punchbowl Street		Honolulu	HI	96813	808–389–7744	808–547–4077
Rancho Spring Medical Center.	36485 Inland Valley Drive		Wildomar	CA	92595		
Rankin Medical Center	350 Crossgates Boulevard		Brandon	MS	39042	601–824–8374	601–824–8378
Rapid City Regional Hospital.	353 Fairmont Boulevard		Rapid City	SD	57702	605–719–1220	605–719–4354
Rapides Regional Medical Center.	211 4th Street Box 30101		Alexandria	LA	71301	318–449–7540	318–449–7524
Redmond Regional Medical Center.	501 Redmond Road		Rome	GA	30165	706–802–3831	1–866–947–1325
Regents of the University of Michigan.	300 N. Ingalls Street 7A10		Ann Arbor	MI	48109	734–998–8208	734–998–8203
Regional Hospital of Jackson.	367 Hospital Boulevard		Jackson	TN	38305	731–661–2124	731–661–2216
Regional Medical Center	225 N. Jackson Avenue		San Jose	CA	95116	408–259–5000 ext. 2181	408–347–4072
Regional Medical Center	3000 St. Matthews Road		Orangeburg	SC	29118	803–395–2960	803–395–2925
Regional Medical Center	900 Hospital Drive		Madisonville	KY	42431–1644	270–825–5183	270–326–5021
Regional Medical Center Bayonet Point.	14000 Fivay Road		Hudson	FL	34667	727–819–2929 x1235	
Regions Hospital	640 Jackson Street	Mail Stop 11102–M.	St. Paul	MN	55101	651–254–3351	651–254–2390
Reid Hospital & Healthcare Services.	1401 Chester Boulevard		Richmond	IN	47374	765–983–3476	765–983–3116
Renown Regional Medical Center.	1155 Mill Street	R 11	Reno	NV	89502	775–982–5833	775–982–5602
Research Medical Center	2316 East Meyer Boulevard.	Cardiology Services.	Kansas City	MO	64132	816–276–4421	816–276–4356
Reston Hospital Center	1850 Town Center Parkway.		Reston	VA	20190	703–689–9071	

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Resurrection Medical Center.	7435 Talcott Avenue		Chicago	IL	60631	773–792–8961	773–792–5179
Rex Hospital	4420 Lake Boone Trail		Raleigh	NC	27607	919–784–3192	919–784–3490
Rhode Island Hospital	593 Eddy Street		Providence	RI	02903	401–444–7193	401–444–7061
Richmond University Medical Center.	355 Bard Avenue		Staten Island	NY	10310	718–818–4352	718–818–4247
Riddle Memorial Hospital	1068 W. Baltimore Pike		Media	PA	19063–5177	610–891–6205	610–891–6255
Rideout Memorial Hospital	726 4th Street		Maryville	CA	95901	530–751–4270 x1455	530–749–4593
Ridgecrest Regional Hospital.	1081 N. China Lake Boulevard.		Ridgecrest	CA	93555	760–499–3926	
Riley Hospital	1102 Constitution Avenue		Meridian	MS	39301	601–484–3577	
Rio Grande Regional Hospital.	101 E. Ridge Road		McAllen	TX	78503	956–632–6731	956–632–6734
River Oaks Hospital	1030 River Oaks Drive		Flowood	MS	39232	601–936–2387	601–936–2249
River Region Medical Center.	2100 Highway 61 North		Vicksburg	MS	39183	601–883–5759	601–883–6828
Riverside Community Hospital.	4445 Magnolia Avenue		Riverside	CA	92501	951–788–3449	
Riverside Medical Center	350 N. Wall Street		Kankakee	IL	60901	815–936–8966	815–802–1351
Riverside Methodist Hospital.	3535 Olentangy River Road.		Columbus	OH	43214	614–566–3757	614–566–6838
Riverside Regional Medical Center.	500 J Clyde Morris Boulevard.		Newport News	VA	23601	757–594–3309	757–594–3547
Riverview Hospital	395 Westfield Road		Noblesville	IN	46060	317–776–7177	
Riverview Regional Medical Center.	600 South Third Street	PO Box 268	Gadsden	AL	35901	256–543–5808	256–543–5535
Robert Packer Hospital	1 Guthrie Square		Gadsden	AL	18840	570–882–4916	570–882–5809
Robinson Memorial Hospital	6847 N. Chestnut Street		Ravenna	OH	44266	330–297–8217	330–297–4086
Rochester General Hospital	1425 Portland Avenue		Rochester	NY	14621	585–922–4693	
Rockford Memorial Hospital	2400 North Rockton Avenue.		Rockford	IL	61103	815–971–6727	815–971–9564
Rogue Valley Medical Cent	2825 E. Barnett Road	Performance Improvement Dept..	Medford	OR	97504	541–789–4815	541–789–4811
Roper Hospital	316 Calhoun Street		Charleston	SC	29401	843–724–2683	843–724–1983
Rose Medical Center	4567 E. 9th Avenue		Denver	CO	80220–3941	303–320–2238	303–320–2645
Round Rock Medical Center.	2400 Round Rock Medical Center.		Round Rock	TX	78681	512–341–5227	
Rush Hospital	1314 19th Avenue		Meridian	MS	39301	601–703–9494	
Rush North Shore Medical Center.	9600 Gross Point Road		Skokie	IL	60076	847–933–6787	847–933–3858
Rush Oak Park Hospital	520 South Maple Avenue		Oak Park	IL	60304–1097	708–660–6665	708–660–6658
Rush University Medical Center.	1653 West Congress Parkway.		Chicago	IL	60612	312–942–6806	312–942–7986
Rush-Copley Medical Center Attn: Health Science Library.		2000 Ogden Avenue.	Alexander City	AL	60504	630–898–5658	
Russell Medical Center	3316 Highway 280 PO Box 939.		Alexander City	AL	35011	256–329–7180	
Rutland Regional Medical Center.	160 Allen Street		Rutland	VT	05701	802–772–2613	
Sacred Heart Hospital of Pensacola.	5151 North 9th Avenue		Pensacola	FL	32504–8721	850–416–7766	850–416–5245
Sacred Heart Hospital Attn: A/P.	900 W. Clairemont Avenue		Eau Claire	WI	54701	715–839–4590	
Sacred Heart Medical Center.	1155 Hilyard Street		Eugene	OR	97401	541–984–4269	
Sacred Heart Medical Center.	101 W. Eighth Avenue		Spokane	WA	99204	509–474–3733	509–474–3741
Saddleback Memorial Medical Center.	24451 Health Center Drive		Laguna Hills	CA	92653	949–452–3867	
Saint Agnes Medical Center	1303 East Herndon Avenue.		Fresno	CA	93720	559–450–3915	
Saint Anthony Medical Center.	1201 S. Main Street		Crown Point	IN	46307	219–757–6162	219–757–6367
Saint Bernadine Medical Center.	2101 N. Waterman Avenue	2101 N. Waterman Avenue.	San Bernadino	CA	92404–4836	909–881–7669	909–881–4534
Saint Clare's Hospital	611 St. Joseph's Avenue		Marshfield	WI	54449	715–389–5130	715–389–3200
Saint Elizabeth Health Center.	1044 Belmont Avenue		Youngstown	OH	44511	330–480–6668	330–480–2572
Saint Elizabeth Hospital	2700 W. 9th Avenue Suite 107.		Oshkosh	WI	54904	920–223–1154	920–223–1180
Saint Elizabeth Medical Center—South.	1 Medical Village Drive		Edgewood	KY	41017–3403	859–301–5672	859–301–3897
Saint Elizabeth Regional Medical Center.	555 S. 70th Street		Lincoln	NE	68510–2462	402–219–7255	402–219–7900
Saint Elizabeth's Hospital	211 South 3rd Street		Belleville	IL	62220–1915	618–234–2120 x2105	618–222–4622
Saint Francis Hospital	2122 Manchester Expressway.		Columbus	GA	31904	706–596–4166	706–596–4351
Saint Francis Hospital	5959 Park Avenue		Memphis	TN	38119	901–765–2358	
Saint Francis Hospital	6161 S. Yale Avenue		Tulsa	OK	74136	918–494–6265	918–494–4199

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Saint Francis Hospital & Health Center.	8111 S. Emerson Avenue		Indianapolis	IN	46237	317–851–1545	317–851–1655
Saint Francis Hospital & Medical Center.	114 Woodland Street		Hartford	CT	06105	860–714–4060	860–714–8001
Saint Francis Hospital and Health Center.	12935 Gregory Street		Blue Island	IL	60406–2470	708–824–4893	708–824–4513
Saint Francis Hospital of Evanston.	355 Ridge Avenue		Evanston	IL	60202	847–316–6245	847–316–4515
Saint John Hospital & Medical Center.	22151 Moross Road	Professional Bldg #1, #126.	Detroit	MI	48236–2148	313–343–7870	313–417–2758
Saint John Macomb—Oakland Hospital.	11800 E. 12 Mile Road	Room # 2510	Warren	MI	48093	586–573–5891	586–573–5841
Saint Johns Mercy Medical Center.	615 S. New Ballas Road		St. Louis	MO	63141	314–251–6544	314–251–4751
Saint Joseph Hospital	2900 N. Lake Shore Drive		Chicago	IL	60657–6274	773–665–3597	773–665–6348
Saint Joseph Hospital	Saint Joseph Hospital & Medical Center.	350 West Thomas Road.	Phoenix	AZ	85013	602–406–6935	
Saint Joseph Hospital	2700 Dolbeer Street		Eureka	CA	95501	707–445–8121 x6240	707–269–3842
Saint Joseph Hospital	3001 W. Martin Luther King Boulevard.		Tampa	FL	33607	813–554–8711	813–870–4663
Saint Joseph Regional Health Center.	2801 Franciscan Street		Bryan	TX	77802–2544	979–776–2941	979–776–4985
Saint Joseph's Hospital	1824 Murdoch Avenue		Parkersburg	WV	26102–0327	304–424–4577	304–424–4643
Saint Josephs Hospital/ Marshfield Clinic.	611 St. Joseph Avenue		Marshfield	WI	54449–1832	715–389–5130	715–389–3200
Saint Joseph's Hospital of Atlanta.	5665 Peachtree Dunwoody Road.		Atlanta	GA	30342	404–851–5059	
Saint Louis University Hospital.	3635 Vista at Grand		Saint Louis	MO	63110	314–577–8204	314–268–5472
Saint Luke's Hospital	1026 A Avenue, North East.		Cedar Rapids	IA	52406–3026	319–369–8005	319–368–5583
Saint Luke's Hospital	4401 Wornall Road (MAHI 5th Floor).		Kansas City	MO	64111	816–932–5692	
Saint Luke's Hospital	232 S. Woods Mill Road		Chesterfield	MO	63017–3417	314–205–6981	314–336–5472
Saint Luke's Regional Medical Center.	190 E. Bannock Street		Boise	ID	83712–6241	208–381–1767	208–381–1631
Saint Margaret Mercy	5454 Hohman Avenue		Hammond	IN	46320	219.933.2120	219.933.2583
Saint Mary Corwin Medical Center.	1008 Minnequa Avenue		Pueblo	CO	81004–3798	719–560–5280	719–560–5789
Saint Mary Mercy Hospital	36475 West Five Mile Road.		Livonia	MI	48154	734–655–2988	734–655–2884
Saint Mary's Hospital	56 Franklin Street		Waterbury	CT	06706	203–709–6375	
Saint Mary's Hospital and Regional Medical Center.	2635 N. 7th Street		Grand Junction	CO	81501–8209	970–244–2312	970–244–7033
Saint Mary's Medical Center.	2900 First Avenue		Huntington	WV	25702	304–526–8794	
Saint Mary's Medical Center.	3700 Washington Avenue		Evansville	IN	47750	812–485–4139	812–485–7030
Saint Mary's Regional Medical Center.	235 W. Sixth Street		Reno	NV	89503	775–770–3929	775–770–3665
Saint Peter's Hospital	315 South Manning Boulevard.		Albany	NY	12208	518–525–1983	
Saint Rita's Medical Center	730 West Market Street		Lima	OH	45801–4602	419–996–5520	419–996–5409
Saint Rose Dominican—Siena Campus.	3001 St. Rose Parkway		Henderson	NV	89052	702–616–5372	
Saint Thomas Health Care Services.	4220 Harding Road		Nashville	TN	37202–0380	615–222–6282	615–222–6285
Saint Vincent Health Center	252 West 25th Street		Erie	PA	16544	814–452–5467	814–452–5651
Saint Vincent Hospital	123 Summer Street	Suite 270	Worcester	MA	01608	508–363–7171	508–363–9621
Saint Vincent Hospital Manhattan.	170 W. 12th Street		New York	NY	10011	212–604–7456	
Saint Vincent Medical Center/Health Center.	2 St. Vincent Circle		Little Rock	AR	72205	501–552–4826	
Saint Vincent's Medical Center.	2800 Main Street		Bridgeport	CT	06606	203–576–6114	203–576–6020
Salem Hospital (Regional Health Services).	665 Winter Street SE		Salem	OR	97301–3919	503–561–5412	
Salina Regional Health Center.	400 S. Santa Fe Avenue		Salina	KS	67401	785–452–6893	785–452–7044
Salinas Valley Memorial Hospital.	450 E. Romie Lane		Salinas	CA	93901–4098	831–757–4333 ext. 2105	831–771–5079
Salt Lake Regional Medical Center.	3580 W. 9000 W		West Jordan	UT	84088	801–562–3188	
San Antonio Community Hospital.	999 San Bernardino Road		Upland	CA	91786	909–920–6117	
San Francisco Heart and Vascular Institute.	1900 Sullivan Avenue		Daly City	CA	94015	650–991–6358	650–755–7315
San Jacinto Methodist Hospital.	4401 Garth Road		Baytown	TX	77521	281–420–7372	
San Joaquin Community Hospital.	2615 Chester Avenue		Bakersfield	CA	93301	661–869–6508	661–869–6935
San Juan Regional Medical Center.	801 W. Maple Street		Farmington	NM	87401	505–324–3373	505–599–4705

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
San Ramon Regional Medical Center.	6001 Norris Canyon Road		San Ramon	CA	94583	625–570–7885	
Sand Lake Hospital	1414 Kuhl Avenue		Orlando	FL	32806	321–841–8047	
Sanford USD Medical Center.	1305 West 18th Street		Sioux Falls	SD	57117	605–328–7873	605–333–1964
Santa Barbara Cottage Hospital.	PO Box 689		Santa Barbara	CA	93102–0689	805–569–8282	805–569–7411
Santa Rosa Memorial Hospital.	1165 Montgomery Drive PO Box 522.		Santa Rosa	CA	95402	704–525–5300 x5890	707–522–1555
Santa Theresa Community Hospital.	250 Hospital Parkway 1st Floor Cath Office.		San Jose	CA	95119	408–972–7492	408–972–7162
Sarasota Memorial Hospital	1700 S. Tamiami Trail		Sarasota	FL	34239	941–917–1331	941–917–6162
Satilla Heart Center	410 Darling Avenue		Waycross	GA	31501	912–287–2625	
Savoy Medical Center	801 Poincianna Street		Mamou	LA	70554	337–468–5261	337–468–3342
Scott and White Hospital	2401 South 31st Street		Temple	TX	76508	254–724–5037	254–724–1799
Scottsdale Healthcare Osborn.	7400 E. Osborn Road		Scottsdale	AZ	85260	480–882–5391	
Scottsdale Healthcare Shea	9003 E. Shea Boulevard—Administration.		Scottsdale	AZ	85260	480–882–5391	
Scripps Green Hospital—La Jolla.	10666 North Torrey Pines Road.		La Jolla	CA	92037	858–554–3618	858–554–3636
Scripps Memorial Hospital—La Jolla.	9888 Genessee Avenue		La Jolla	CA	92037	858–626–7057	858–626–4112
Scripps Mercy Hospital—San Diego.	4077 5th Avenue	MER 74	San Diego	CA	92103	619–686–3462	619–260–7047
Scripps Mercy Hospital—Chula Vista.	435 H Street		Chula Vista	CA	91910	619–691–7278	619–407–7666
Sebastian River Medical Center.	13695 US Highway 1		Sebastian	FL	32962	772–581–2019	772–388–3689
Self Regional Healthcare	1325 Spring Street		Greenwood	SC	29646	864–725–7004	
Sentara Norfolk General Hospital.	600 Gresham Drive		Norfolk	VA	23507	757–668–2035	757–668–3579
Sentara Obici Hospital	2800 Goodwin Boulevard		Suffolk	VA	23434	757–388–2035	757–388–3579
Sentara Virginia Beach General Hospital.	1060 First Colonial Road		Virginia Beach	VA	23454–0685	757–395–6783	757–395–8725
Sequoia Hospital	Whipple and Alameda Avenues.	170 Alameda de Las Pulgas.	Redwood City	CA	94062	650–367–5925	650–482–6187
Seton Medical Center	1201 W. 38th Street		Austin	TX	78705	512–324–1000 x17713	512–324–1083
Shady Grove Adventist Hospital.	9901 Medical Center Drive		Rockville	MD	20850	301–279–6188	240–453–5915
Shands at AGH	801 SW 2nd Avenue		Gainesville	FL	32601	352–338–7177	352–338–7122
Shands Jacksonville Medical Center.	655 West 8th Street		Jacksonville	FL	32209	904–244–3304	904–244–3102
Sharon Regional Health System.	740 E. State Street		Sharon	PA	16146	724–983–3911	724–983–3965
Sharp Chula Vista Medical Center.	8695 Spectrum Center Court.		San Diego	CA	92123	619–482–5867	
Sharp Grossmont	5555 Grossmont Center Drive.		La Mesa	CA	91942	619–740–4123	619–740–4213
Sharp Memorial Hospital	7901 Frost Street		San Diego	CA	92123	858–939–6713	
Shasta Regional Medical Center.	1100 Butte Street		Redding	CA	96001	530–244–8200	
Shawnee Mission Medical Center.	9100 West 74th Street		Shawnee Mission	KS	66204–4004	913–676–2052	913–789–3190
Shelby Baptist Medical Center.	1000 First Street North		Alabaster	AL	35007	205–620–8184	205–620–7003
Sherman Hospital	934 Center Street	Decision Support	Elgin	IL	60120	847–429–1248	847–429–2816
Shore Health System of Maryland.	219 South Washington Street.		Easton	MD	21601	410–822–1000 x5810	
Sierra Medical Center	1625 Medical Center Drive		El Paso	TX	79902	915–747–2873	915–747–2716
Sierra Vista Regional Medical Center.	1010 S. Murray Avenue		San Luis Obispo	CA	93405	805–546–5122	805–546–5106
Silver Cross Hospital	1200 Maple Road		Joliet	IL	60432	815–740–7104	
Simi Valley Hospital & Health Care Services.	2975 North Sycamore Drive.		Simi Valley	CA	93065	805–955–6000	
Sinai—Grace Hospital	6071 W. Outer Drive		Detroit	MI	48235	313–966–6870	
Sinai Hospital of Baltimore	2401 West Belvedere Avenue.		Baltimore	MD	21215–5271	410–601–8140	
Singing River Hospital	3109 Bienville Boulevard		Ocean Springs	MS	39564	228–818–5000	
Skaggs Community Health Center.	PO Box 650		Branson	MO	65615–0650	417–335–7442	417–335–7131
Sky Ridge Medical Center	10101 Ridgegate Parkway		Lone Tree	CO	80124	720–225–1865	720–225–1869
Skyline Medical Center/HTI Memorial Hospital Corp.	3441 Dickerson Pike		Nashville	TN	37207	615–769–4450	615–769–4451
Smith of Georgia, LLC d.b.a. Smith Northview Hopsital.	PO Box 10010		Valdosta	GA	31604	229–671–2016	229–671–2054
Somerset Hospital	225 South Center Avenue		Somerset	PA	15501–2088	814–443–5390	814–443–5768
Sound Shore Medical Center.	16 Guion Place		New Rochelle	NY	10801	914–365–4733	914–638–1393
South Bay Hospital	4016 Sun City Center Boulevard.		Sun City Center	FL	33570	813–634–0280	

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
South Crest Hospital	8801 S. 101st E Avenue		Tulsa	OK	74133	918–294–4677	918–294–4943
South Fulton Medical Center.	1170 Cleveland Avenue		East Point	GA	30344	404–466–6404	404–466–6420
South GA Medical Center	PO Box 1727		Valdosta	GA	31603–1727	912–259–4340	912–259–4341
South Miami Hospital	6200 SW 73rd Street		Miami	FL	33143	786–662–5300	786–662–5138
South Nassau Communities Hospital.	One Healthy Way		Oceanside	NY	11572	516–632–3418	516–336–2943
South Shore Hospital	55 Fogg Road		South Weymouth	MA	02190–2432	781–340–8501	781–340–8826
Southeast Alabama Medical Center.	1108 Ross Clark Circle		Dothan	AL	36301	334–793–8188	
Southeast Baptist Hospital	4214 E. Southcross Boulevard.		San Antonio	TX	78222	210–297–1264	210–297–0926
Southeast Missouri Hospital	1701 Lacey Street		Cape Girardeau	MO	63701	573–651–5557	573–986–5978
Southern Hills Hospital	9300 West Sunset Road		Las Vegas	NV	89148	702–880–2147	
Southern New Hampshire Medical Center.	8 Prospect Street		Nashua	NH	03060	603–577–2320	603–577–2909
Southern Ohio Medical Center.	1805 27th Street		Portsmouth	OH	45662	740–356–8573	740–354–2798
Southern Regional Medical Center.	11 Upper Riverdale Road SW.		Riverdale	GA	30274	770–991–8682	770–991–8619
Southlake Hospital	1099 Citrus Tower Boulevard.		Clermont	FL	34711	352–241–7276	352–241–7107
Southside Hospital	301 East Main Street		Bayshore	NY	11706	631–968–3009	631–968–3177
Southwest Florida Regional Medical Center.	636 Del Prado Boulevard Suite 104.		Cape Coral	FL	33990	239–573–5548	239–573–5542
Southwest General Health Center.	18697 Bagley Road		Middleburg Heights.	OH	44130–3417	440–816–4760	440–816–5768
Southwest General Hospital	7400 Barlite Boulevard		San Antonio	TX	78224	210–921–3385	210–921–3438
Southwest Medical Center	2810 Ambassador Caffrey Parkway.		Lafayette	LA	70506	337–981–2949 x1274	
Southwest MS Regional Medical Center.	303 Marion Avenue		McComb	MS	39648	601–249–1832	601–249–1835
Southwest Washington Medical Center.	600 NE 92nd Avenue		Vancouver	WA	98664	360–514–3372	360–514–1852
Spalding Regional Medical Center.	601 South 8th Street		Griffin	GA	30224	770–233–2013	
Sparks Regional Medical Center.	P O Box 17006	1001 Towson	Fort Smith	AR	72917–7006	479–573–2330	479–441–4877
Sparrow Health System	1215 East Michigan Avenue.		Lansing	MI	48909–7980	517–364–2506	517–484–9759
Spartanburg Regional Medical Center.	101 East Wood Street	Cardiac Cath Lab/ 3rd Floor Heart Center.	Spartanburg	SC	29303	864–560–8345	864–560–6007
Spectrum Health	100 Michigan Street NE	MC 037, Rm 3825A.	Grand Rapids	MI	49503–2560	616–391–2458	616–391–2761
Spring Branch Medical Center.	8850 Long Point Road		Houston	TX	77055	713–722–3214	713–722–3785
Spring Valley Hospital	5400 S. Rainbow Boulevard.		Las Vegas	NV	89118	702–853–3162	702–853–8606
Springfield Regional Medical Center, Fountain Camp.	1343 North Fountain Boulevard.		Springfield	OH	45503	937–328–9319	937–328–8788
Springhill Memorial Hospital	3719 Dauphin Street		Mobile	AL	36608	251–460–5326	251–461–4126
Springs Memorial Hospital	800 West Meeting Street		Lancaster	SC	29720	803–286–1671	803–313–3152
SSM St. Joseph Health Center.	300 First Capitol Drive		St. Charles	MO	63301	314–518–0751	636–947–5684
SSM St. Joseph Hospital of Kirkwood.	525 Couch Avenue		Kirkwood	MO	63122	314–966–1578	314–256–6451
St. Anthony Central Hospital.	4231 W. 16th Avenue		Denver	CO	80204–1335	303–629–2288	303–595–6912
St. James Hospital and Health Centers.	20201 S. Crawford Avenue		Olympia Fields	IL	60461	708–679–2033	
St. Joseph Hospital	700 Broadway		Fort Wayne	IN	46802	260–425–3425	
St. Joseph Hospital—Oakland.	44405 Woodward Avenue		Pontiac	MI	48341–5023	248–858–6038	248–858–3288
St. Joseph Medical Center	1717 South J Street		Tacoma	WA	98405–4933	253–426–6046	253–426–6440
St. Josephs Hospital	69 W. Exchange Street		St Paul	MN	55102	651–326–3088	651–232–3296
St. Joseph Hospital Health Center.	301 Prospect Avenue		Syracuse	NY	13203	315–448–5832	315–448–5656
St. Luke's Cornwall Hospital	70 DuBois Street		Newburgh	NY	12550	845–568–2094	845–568–2980
St. Mary's Health Care Systems.	1230 Baxter Street		Athens	GA	30606	706–389–2284	706–389–2285
St. Mary's Hospital	400 North Pleasant		Centralia	IL	62801	618–436–8980	618–436–8052
St. Mary's Regional Medical Center.	305 S. 5th Street		Enid	OK	73701	580–249–3026	580–249–3994
St. Vincent Mercy Medical Center.	2213 Cherry Street		Toledo	OH	43608	419–251–2761	
St. Agnes Hospital	900 Caton Avenue		Baltimore	MD	21229	410–368–2822	410–368–3220
St. Alexius Medical Center	1555 Barrington Road		Hoffman Estates	IL	60194–1018	847–755–8678	847–755–8499
St. Alphonsus Regional Medical Center.	1055 N. Curtis Road		Boise	ID	83706	208–367–2930	208–367–4270
St. Anthony Hospital	1000 N. Lee Avenue		Oklahoma City	OK	73102	405–272–7394	405–272–7169
St. Anthony's Health Care	1200 7th Avenue North	MS 2019	St. Petersburg	FL	33705	727–825–1520	727–825–1518

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
St. Anthony's Medical Center.	10010 Kennerly Road		St. Louis	MO	63128–2106	314–525–1834	
St. Barnabas Medical Center.	94 Old Short Hills Road		Livingston	NJ	07039	973–322–5562	973–422–0723
St. Bernards Medical Center.	225 E. Jackson Avenue		Jonesboro	AR	72401	870–972–4147	870–974–7021
St. Catherine Hospital East Chicago.	1500 South Lake Park Avenue.		Hobart	IN	46342	219–947–6767	219–947–6769
St. Catherine of Siena	50 Route 25A		Smithtown	NY	11787	631–862–3510	631–862–3802
St. Charles Medical Center	2500 North East Neff Road		Bend	OR	97701–6015	541–318–4985	541–383–6825
St. Clair Hospital	St. Clair Hospital	1000 Bower Hill Road.	Pittsburgh	PA	15243	412–942–2267	
St. David's Medical Center	919 East 32nd Street		Austin	TX	78765	512–370–4420	
St. David's South Austin Hospital.	901 W. Ben White Boulevard.		Austin	TX	78704	512–448–7373	512–448–7498
St. Dominic-Jackson Memorial Hospital.	969 Lakeland Drive		Jackson	MS	39216	601–200–2713	
St. Edwards Mercy Medical Center.	7301 Rogers Avenue		Ft. Smith	AR	72917–7000	479–314–5682	479–314–1447
St. Elizabeth Hospital	2233 W. Division Street		Chicago	IL	60622	312–770–2244	312–770–2030
St. Elizabeth Hospital Medical Center.	1501 Hartford Street		Lafayette	IN	47904	765–423–6298	765–423–6293
St. Elizabeth Medical Center.	2209 Genesee Street		Utica	NY	13501	315–734–3335	315–734–3072
St. Francis Health Center	1700 SW 7th Street		Topeka	KS	66605	785–295–7828	785–231–5992
St. Francis Hospital	One St. Francis Drive		Greenville	SC	29601	864–255–1079	864–255–1762
St. Francis Hospital	701 N. Clayton Street		Wilmington	DE	19805	302–421–4395	302–421–4397
St. Francis Hospital	333 Laidley Street	PO Box 44 Culloden, WV 25510.	Charleston	WV	25322	304–347–6500 ext. 6675	304–347–6153
St. Francis Hospital	100 Port Washington Boulevard.		Roslyn	NY	11576	516–562–6252	516–562–6178
St. Francis Medical Center	211 Saint Francis Drive		Cape Girardeau	MO	63703–5049	573–331–5286	573–331–5023
St. Francis Medical Center	3630 Imperial Highway		Lynwood	CA	90265	310–900–8641	310–885–5938
St. Francis Medical Center	309 Jackson Street		Monroe	LA	71201	318–327–5243	318–327–4144
St. Francis Medical Center	601 Hamilton Avenue		Trenton	NJ	08629	609–599–5771	609–599–5715
St. Francis North Hospital	309 Jackson Street		Monroe	LA	71201	318–327–5243	
St. Helena Hospital	10 Woodland Road		St. Helena	CA	94574	707–967–6325	707–967–5744
St. James Health Care	400 South Clark Street		Butte	MT	59701	406–723–2794	
St. John Medical Center	1923 S. Utica Avenue	Heart Institute Education/Research.	Tulsa	OK	74104	918–744–2825	918–744–3281
St. John Medical Center	1615 Delaware Street		Longview	WA	98632	360–636–4823	360–414–2739
St. John Providence Hospital.	16001 W. Nine Mile Road		Southfield	MI	48075	248–849–2076	248–849–2853
St. John West Shore Hospital.	29000 Center Ridge Road		Westlake	OH	44145	440–827–5506	440–827–5110
St. John's Hospital	800 E. Carpenter Street		Springfield	IL	62769	217–544–6464 x47139	217–535–3885
St. John's Hospital	1235 East Cherokee Street		Springfield	MO	65804	417–820–7523	417–820–7786
St. John's Pleasant Valley Hospital.	2309 Antonio Avenue		Camarillo	CA	93010	805–988–2500 x2099	805–981–4403
St. John's Queens Hospital	90–02 Queens Boulevard		Elmhurst	NY	11373	718–558–0032	718–558–1878
St. Johns Regional Medical Center.	2727 McClelland Boulevard.		Joplin	MO	64804	417–625–2215	417–659–6704
St. Johns Regional Medical Center.	1600 N. Rose Avenue		Oxnard	CA	93030–3722	805–988–2500 x2099	805–981–4403
St. John's Riverside Hospital.	967 North Broadway	Health Information Services.	Yonkers	NY	10701	914–964–4350	914–964–4929
St. Joseph Hospital	172 Kinsley Street		Nashua	NH	03060	603–882–3000 x67117	
St. Joseph Hospital	360 Broadway		Bangor	ME	04401	207–262–1403	207–262–2422
St. Joseph Hospital	1 Saint Joseph Drive		Lexington	KY	40504	859–313–2395	859–313–4337
St. Joseph Hospital	2901 Squalicum Parkway		Bellingham	WA	98225	360–734–5400 x3504	360–738–6733
St. Joseph Intercommunity Hospital.	2605 Harlem Road		Cheektowaga	NY	14225	716–891–2683	716–891–2688
St. Joseph Medical Center	12th & Walnut Streets		Reading	PA	19603	610–378–2340	610–378–2530
St. Joseph Medical Center	1401 St. Joseph Parkway		Houston	TX	77002	713–757–7418	713–757–7420
St. Joseph Medical Center	7601 Olser Drive		Towson	MD	21204	410–337–1509	410–337–3947
St. Joseph Mercy Hospital	5325 Elliot Drive		Ann Arbor	MI	48106	734–712–2728	734–712–8689
St. Joseph Reg. Medical Center.	801 E. Lasalle Avenue		South Bend	IN	46617	574–237–7979	574–282–8960
St. Joseph Regional Medical Center.	703 Main Street		Paterson	NJ	07503	973–754–3559	973–754–2342
St. Joseph's Hospital	11705 Mercy Boulevard		Savannah	GA	31419	912–819–5291	912–691–9066
St. Joseph's Hospital	350 N. Wilmot Road		Tucson	AZ	85711	520–696–2529	
St. Joseph's Medical Center	127 S. Broadway		Yonkers	NY	10701	914–378–7499	914–965–4838
St. Josephs Medical Center of Stockton.	1805 North California Street Suite 303.	Suite #303	Stockton	CA	95204	209–461–5375	209–461–3462
St. Josephs Mercy Health Center.	300 Werner Drive		Hot Springs	AR	71913	501–622–1489	501–622–2334
St. Jude Medical Center	101 East Valencia Mesa		Fullerton	CA	92835	714.992.3000 ext. 5346	714.446.5120

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
St. Luke Hospital East	85 N. Grand Avenue		Ft. Thomas	KY	41075	859–572–3905	859–572–2355
St. Luke Hospital West	7380 Turfway Road		Florence	KY	41042	859–962–5200	
St. Luke's Baptist Hospital	7830 Floyd Curl Drive		San Antonio	TX	78229	210–297–1264	210–297–0926
St. Luke's Community Medical Center (The Woodlands).		17200 St. Luke's Way.	The Woodlands	TX	77384	936–266–3964	936–266–2009
St. Luke's Episcopal Hospital.	3100 Main Street	MC5–313	Houston	TX	77030	832–355–7276	832–355–3965
St. Lukes Hospital	363 Higland Avenue		Falls River	MA	02720	508–679–7159	
St. Lukes Hospital	5901 Monclova Road		Maumee	OH	43537	419–893–5951	419–897–8381
St. Luke's Hospital	915 E. First Street		Duluth	MN	55805	218–249–6024	218–249–5110
St. Luke's Hospital & Health Network.	801 Ostrum Street		Bethlehem	PA	18015	610–954–4630	610–954–4631
St. Luke's Hospital and Health Network (Allentown Campus).	1736 Hamilton Boulevard		Allentown	PA	18104	610–954–4640	610–954–2537
St. Luke's Hospital—Mayo Clinic.	4201 Belfort Road		Jacksonville	FL	32216	904–296–4125	
St. Luke's Medical Center	2901 West Oklahoma Avenue.		Milwaukee	WI	53215–4330	414–649–6807	
St. Luke's South Hospital	12300 Metcalf Avenue		Overland Park	KS	66213	913–317–7494	
St. Luke's—Roosevelt Hospital Center.	1111 Amsterdam Avenue		New York City	NY	10025	212–523–3755	212–523–2991
St. Mark's Hospital/ Northern Utah Healthcare Corporation.	6985 Union Park Center		Cottonwood Heights.	UT	84047	801–268–7265	
St. Mary Hospital	1201 Langhorne Newton Road.		Langhorne	PA	19047	215–710–5735	
St. Mary Medical Center	18300 Highway 18		Appple Valley	CA	92307	760–946–8165	760–946–8867
St. Mary Medical Center	1050 Linden Avenue		Long Beach	CA	90813–3321	562–491–9052	562–491–9795
St. Mary Medical Center	1500 South Lake Park Avenue.		Hobart	ID	46342	219–947–6767	219–947–6769
St. Mary of Nazareth Hospital Center.	2233 W. Division Street		Chicago	IL	60622	312–770–2244	312–770–2030
St. Mary's Health Center	6420 Clayton Road		St. Louis	MO	63117	314–768–8874	314–768–7122
St. Mary's Hospital	707 S. Mills Street		Madison	WI	53715–1849	608–259–3473	608–229–7178
St. Mary's Hospital	1800 East Lake Shore Drive.		Decatur	IL	62521	217–464–2402	
St. Mary's Hospital (Passaic).	350 Boulevard		Passaic	NJ	07055	973–365–4323	973–365–4375
St. Mary's Medical Center	901 45th Street		West Palm Beach	FL	33407	561–882–2710	
St. Mary's Medical Center	450 Stanyan Street		San Francisco	CA	94117	415–750–5551	415–750–5825
St. Mary's Medical Center	900 E. Oak Hill Avenue		Knoxville	TN	37917	865–545–8177	
St. Mary's Medical Center	407 East Third Street		Duluth	MN	55805	218–786–4129	218–786–4834
St. Mary's of Michigan	800 S. Washington Avenue		Saginaw	MI	48601	989–907–8409	
St. Michael's Medical Center.	111 Central Avenue		Newark	NJ	07102	973–877–5153	
St. Nicholas Hospital	3100 Superior Avenue		Sheboygan	WI	53081	920–451–7466	920–452–8336
St. Patrick Hospital and Health Sciences Center.	500 W. Broadway		Missoula	MT	59802	406–329–5770	406–329–5652
St. Rose Hospital	27200 Calaroga Avenue		Hayward	CA	94539	510–264–4505	510–264–4213
St. Tammany Parish Hospital.	1202 S. Tyler Street		Covington	LA	70433	985–898–4005	
St. Vincent Charity Hospital	2351 East 22nd Street		Cleveland	OH	44115	216–363–2532	216–363–2783
St. Vincent Healthcare	1233 N. 30th Street		Billings	MT	59101	406–237–4360	406–237–4390
St. Vincent Hospital	810 St. Vincents Drive		Birmingham	AL	35205	205–939–7814	205–930–2689
St. Vincent Medical Center	2131 W. 3rd Street		Los Angeles	CA	90703	213–207–5667	
St. Vincent's Medical Center.	1800 Barrs Street		Jacksonville	FL	32204	904–308–3863	
St. Vincent's East	50 Medical Park East Drive		Birmingham	AL	35235–3499	205–838–3463	205–838–3708
Stacia Hansen	45 Reade Place		Poughkeepsie	NY	12601	845–437–3180	845–437–3144
Stanford Hospital and Clinics.	Falk Building 2nd Floor 300 Pasteur Drive.		Stanford	CA	94305	650 736–7920	650 725–3846
Staten Island University Hospital.	475 Seaview Avenue		Staten Island	NY	10305	718–226–1719	718–226–1733
Stony Brook University Medical Center.	3 Technology Drive		East Setauket	NY	11733–4073	631–444–5289	
Stormont-Vail Regional Medical Center.	929 SW Mulvane Street		Topeka	KS	66606	785–270–4103	785–270–4105
Straub Clinic & Hospital: Cath Lab.	888 S. King Street		Honolulu	HI	96813	808–522–3626	808–522–2370
Stringfellow Memorial Hospital.	301 East 18th Street		Anniston	AL	36202	256–235–8935	
Suburban Hospital	8600 Old Georgetown Road.		Bethesda	MD	20814	301–896–2857	301–493–4259
Summerlin Hospital Medical Center.	657 Town Center Drive		Las Vegas	NV	89144		
Summit Healthcare Regional Medical Center.	2200 East Show Low Lake Road.		Show Low	AZ	85901	928–537–6518	
Summit Medical Center	East Main & South 20th Streets.		Van Buren	AR	72956	479–471–4435	
Sun Coast Hospital	2025 Indian Rocks Road S		Largo	FL	33774–1096	727–586–7124	
Sun Health Boswell Hospital.	10401 West Thunderbird Boulevard.		Sun City	AZ	85351	623–875–6560	623–815–6095

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Sunrise Hospital and Medical Center.	3186 S. Maryland Parkway		Las Vegas	NV	89109	702–892–3695	
Sutter Delta Medical Center	3901 Lone Tree Way		Antioch	CA	94509	925–779–3092	
Sutter Medical Center—Sacramento.	5151 F Street 1 South	Transplant & Heart Specialty Clinics.	Sacramento	CA	95819	916–733–0909	
Sutter Medical Center of Santa Rosa.	3325 Chanate Road		Santa Rosa	CA	95404	707–576–4093	707–576–5550
Swedish American Hospital	1401 E. State Street		Rockford	IL	61104	815–961–2382	815–489–4069
Swedish Covenant Hospital	5145 N. California Avenue		Chicago	IL	60625	773–878–8200 x5702	
Swedish Health Services	500 17th Avenue #A85C		Seattle	WA	98104	206–386–6057	
Swedish Medical Center	501 East Hampden Avenue.		Englewood	CO	80113	303–788–4804	303–788–5085
T. J. Samson Community Hospital.	1301 North Race Street		Glasgow	KY	42141	270–651–4868	
Tacoma General Hospital	315 Martin Luther King, Jr. Way.		Tacoma	WA	98415	253–403–3437	253–403–2461
Tahlequah City Hospital	1400 East Downing Street		Tahlequah	OK	74465–1008	918–453–2155	
Tallahassee Memorial Hospital.	1300 Miccosukee Road	Attn: Performance Improvement.	Tallahassee	FL	32308	850–431–4942	850–431–4949
Tampa General Hospital	PO Box 1289		Tampa	FL	33601–1289	813–844–4352	813–844–7963
Temple University Hospital	3401 North Broad Street	1st Floor Room B–150.	Philadelphia	PA	19140	215–707–5501	215–707–3535
Terre Haute Regional Hospital.	3901 South 7th Street		Terre Haute	IN	47802	812–237–9866	812–237–1365
Terrebonne General Medical Center.	8166 Main Street		Houma	LA	70360	985–873–4189	985–873–4256
Texoma Medical Center	1000 Memorial Drive		Denison	TX	75020	903–416–4120	
TexSAn Heart Hospital	6700 IH–10 West		San Antonio	TX	78201–2009	210–736–8008	210–736–8400
The Christ Hospital	2139 Auburn Avenue		Cincinnati	OH	45219	513–585–2840	513–585–3296
The George Washington University Hospital.	900 23rd Street, NW		Washington	DC	20037	202–715–5320	202–715–5083
The Heart Hospital Baylor Plano.	1100 Allied Drive		Plano	TX	75093	469–814–3530	
The Heart Hospital of Northwest Texas.	1501 S. Coulter Street	PO Box 1110	Amarillo	TX	79175	806–351–5837	806–351–5147
The Hospital at WestlakeMedical Center.	5656 Bee Caves Road M–302.		Austin	TX	78746	512–697–3582	512–697–3583
The Indiana Heart Hospital	8075 North Shadeland Avenue.		Indianapolis	ID	46250	317–621–8723	317–621–8706
The Medical Center (TMC)	1000 Dutch Ridge Road		Beaver	PA	15009	724–773–8225	
The Medical Center of Southeast Texas.	2555 Jimmy Johnson Boulevard.		Port Arthur	TX	77640	409–853–5356	409–853–5355
The Methodist DeBakey Heart Center.	6565 Fannin Street		Houston	TX	77030	713–441–2592	
The Monroe Clinic	515 22nd Avenue		Monroe	WI	53566	608–324–1327	608–324–1722
The Mount Sinai Hospital of Queens.	25–11 30th Avenue		Long Island City	NY	11102	718–267–4226	
The Mount Sinai Medical Center.	The Mount Sinai Medical Center.		New York	NY	10029	212–241–7272	212–534–2776
The Nebraska Medical Center.	987551 Nebraska Medical Center.		Omaha	NE	68198	402–552–2314	402–552–2789
The Reading Hospital and Medical Center.	Sixth Avenue and Spruce Street.		West Reading	PA	19611	610–988–8923	610–988–8636
The Toledo Hospital	2142 North Cove Boulevard.	Jobst Tower Suite 200.	Toledo	OH	43606	419–291–5968	
The Valley Hospital	223 North Van Dien Avenue.		Ridgewood	NJ	07450	201–291–6037	201–291–6046
The Washington Hospital	155 Wilson Avenue		Washington	PA	15301–3398	724–223–3570	
The Western Pennsylvania Hospital.	4800 Friendship Avenue	CVI	Pittsburgh	PA	15224	412–578–5366	412–578–4624
The Wisconsin Heart Hospital, Inc.	WFH Clinical Data Management and Analysis.	5000 West Chambers, M229.	Milwaukee	WI	53210	414–447–2727	414–874–4386
Thomas Jefferson University Hospital.	TJUH	111 S. 11th Street Gibbon Building.	Philadelphia	PA	19107	215–955–2532	215–923–4942
Tift Regional Medical Center.	PO Box 747	901 E. 18th Street	Tifton	GA	31794	229–353–6762	229–353–6098
Tobey Hospital	363 Highland Avenue		Fall River	MA		508–679–7153	
Tomball Regional Hospital	605 Holderrieth Boulevard		Tomball	TX	77375	281–401–7553	281–357–2274
Torrance Memorial Medical Center.	3330 Lomita Boulevard		Torrance	CA	90505	310–784–4937	310–784–3775
Tri-City Medical Center	4002 Vista Way		Oceanside	CA	92056	760–940–7802	
Trident Regional Medical Center.	9330 Medical Plaza Drive		Charleston	SC	29406	843–847–4981	843–847–4169
Trinity Hospitals	PO Box 5020		Minot	ND	58702	701–857–5766	701–857–3576
Trinity Medical Center	Attn: CardioVascular Services.	800 Montclair Road.	Birmingham	AL	35213	205–592–5623	
Trinity Medical Center	4602 3rd Street		Moline	IL	61265	309–779–3902	309–779–5222
Trinity Medical Center West	4000 Johnson Road		Steubenville	OH	43952	740–264–8192	740–264–8654
Trinity Regional Medical Center.	802 Kenyon Road		Fort Dodge	IA	50501	515–574–6459	515–574–6036
Trinity Regional Medical Center.	4602 3rd Street		Moline	IL	61265	309–779–3902	309–779–5222

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Tucson Heart Hospital	4888 North Stone Avenue		Tucson	AZ	85704	520–696–2529	
Tucson Medical Center	5301 E. Grant Road		Tucson	AZ	85712	520–324–3527	
Tufts Medical Center	750 Washington Street		Boston	MA	02111	617–636–2811	
Tulane Medical Center	1415 Tulane Avenue		New Orleans	LA	70112	504–988–1407	504–799–7973
Tuomey Healthcare System Tuomey Regional Medical Center.	129 N. Washington Street		Sumter	SC	29150	803–778–9450	
UC San Diego Medical Center.	200 W. Arbor Drive		San Diego	CA	92103	619–543–5726	
UMASS Memorial Medical Center.	55 Lake Ave North		Worcester	MA	01655–0002	508–334–7361	508–856–6571
Union Hospital	1606 N. 7th Street		Terre Haute	IN	47804	812–238–7582	
Union Memorial Hospital	201 E. University Parkway		Baltimore	MD	21218–2891	410–554–6550	410–554–6599
United Health Services Hospitals/Wilson Regional Medical Center.	33–57 Harrison Street	Decker 4 Lobby	Johnson City	NY	13790	607–763–6197	607–763–5335
United Hospital	333 N. Smith Avenue		St. Paul	MN	55102	651–241–8544	651–241–2666
United Hospital Center, Inc.	PO Box 1680		Clarksburg	WV	53143	262–656–3110	262–656–3141
United Hospital System	6308 8th Avenue		Kenosha	WI	53143	262–656–3110	262–656–3141
United Regional Healthcare System.	1600 11th Street		Wichita Falls	TX	76301	940–764–2850	940–764–2865
Unity Health Center	1102 West MacArthur		Shawnee	OK	74804	405–878–3486	405–878–3484
Unity Hospital	550 Osbourne Road NE		Minneapolis	MN	55432	612–262–6028	612–262–4370
Unity Hospital	1555 Long Pond Road		Rochester	NY	14626	585–723–7312	585–368–4973
University Community Hospital.	3100 East Fletcher Avenue		Tampa	FL	33613	813–615–7845	813–615–8107
University Community Hospital Carrollwood Campus.	3100 East Fletcher Avenue		Tampa	FL	33613	813–615–7845	813–615–8107
University Hospital	620 19th Street South		Birmingham	AL	35249	205–934–8716	205–924–8720
University Hospital	234 Goodman Street		Cincinnati	OH	45219	513–584–0295	513–584–2242
University Hospital	1350 Walton Way		Augusta	GA	30901	706–774–7764	706–774–7640
University Hospitals Bedford Medical Center.	44 Blaine Avenue		Bedford	OH	44146	440–735–3526	440–735–3527
University Hospitals Case Medical Center.	11100 Euclid Avenue		Cleveland	OH	44106	216–844–7924	216–844–1419
University Hospitals Geauga Medical Center.	13207 Ravenna Road		Chardon	OH	44024	440–285–6372	440–285–3230
University Hospitals Richmond Medical Center.	27100 Chardon Road		Richmond Heights.	OH	44143	440–585–6115	440–585–6293
University Hospital UMDNJ	150 Bergen Street		Newark	NJ	07101	973–972–1662	973–972–7414
University Medical Center	1501 N. Campbell Avenue		Tucson	AZ	85724	520–694–6899	520–694–2617
University Medical Center	602 Indiana Avenue		Lubbock	TX	79410	806–775–9274	
University Medical Center LSU.	2390 W. Congress Street		Lafayette	IA	70506	337–261–6333	337–261–6334
University Medical Center of Las Vegas.	1800 W. Charleston Boulevard.		Las Vegas	NV	89102	702–383–2348	702–383–2658
University of Califorina, Irvine Division of Cardiology.	101 The City Drive		Orange	CA	92868	714–456–5984	
University of California (UCLA).	18033 Le Conte Avenue		Los Angeles	CA	90095	310–825–6536	
University of California Davis Medical Center.	2315 Stockton Boulevard Main Hospital, Rm 6312.		Sacramento	CA	95817	916–734–7279	916–734–5378
University of California San Francisco Medical Center.	505 Parnassus Avenue L–523 Box 0210.		San Francisco	CA	94143–0210	415–353–7832	415–353–8713
University of Chicago Hospitals.	5841 S. Maryland Avenue		Chicago	IL	60637	773–834–0283	773–834–5923
University of Colorado Hospital Authority.	16205 E. 16th Avenue	Box 132	Aurora	CO	80045	720–848–7546	
University of CT Health Center/John Dempsey Hospital.	263 Farmington Avenue		Farmington	CT	06030	860–679–4117	860–679–4256
University of Florida (Shands)College of Medicine.	1600 SW Archer Road		Gainesville	FL	32610	352–265–0119	352–265–0314
University of Illinois Medical Center at Chicago.	1740 W. Taylor Street	Bld 949 Rm 2181	Chicago	IL	60610	312–996–3839	312–413–7904
University of Iowa Hospitals and Clinics.	200 Hawkins Drive		Iowa City	IA	52242	319–353–6810	
University of Kentucky	800 Rose Street		Lexington	KY	40536	859–323–4738	859–257–7383
University of Louisville Hospital.	530 S. Jackson Street		Loiusville	KY	40202	502–562–3715	
University of Maryland Medical Center Cardiology.	22 S. Greene Street		Baltimore	MD	21201–1544	410–328–1044	410–328–1717
University of Minnesota Medical Center Fairview.	420 Delaware Street SE MMC 815.		Minneapolis	MN	55455	612–273–5592	612–273–8467
University of Mississippi Medical Center.	2500 N. State Street		Jackson	MS	39216	601–984–2250	301–984–2631
University of Missouri Hospital and Clinics.	1 Hospital Drive		Columbia	MO	65212	573–882–2297	573–884–1999
University of North Carolina Hospitals.	UNC Hospitals	101 Manning Drive CB#7075.	Chapel Hill	NC	27514	919–966–9421	919–966–6955
University of Rochester Medical Center.	601 Elmwood Avenue		Rochester	NY	14642	585–273–4453	

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
University of South Alabama Cardiology Department.	2451 Fillingim Street		Mobile	AL	36617	251–471–7361	251–470–1685
University of Tennessee Medical Center.	1924 Alcoa Highway		Knoxville	TN	37920–6999	865–544–9785	865–525–3742
University of Texas Medical Branch at Galveston.	301 University Boulevard		Galveston	TX	77555–0294	409–747–2194	409–772–5141
University of Texas Southwestern—University Hospital.	5323 Harry Hines Boulevard.		Dallas	TX	75390–9013	214–645–5552	214–645–5537
University of Toledo Medical Center.	3065 Arlington Avenue	DH2261	Toledo	OH	43614	419–383–5150	419–383–3149
University of Utah Hospitals and Clinics.	50 North Medical Drive		Salt Lake City	UT	84132	801–585–9940	
University of Virginia Medical Center.	PO Box 800679		Charlottesville	VA	22908–0679	434–243–6825	434–982–3885
University of Washington Medical Center.	1959 NE Pacific Street		Seattle	WA	98195–6422	206–598–0531	
University of Wisconsin Hospital & Clinics.	600 Highland Avenue MC 3204.		Madison	WI	53792	608–890–8618	
UPMC Mercy	1400 Locust Street		Pittsburgh	PA	15219	412–232–8440	
UPMC Passavant Hospital	9100 Babcock Boulevard		Pittsburgh	PA	15237	412–635–3878	
UPMC Presbyterian Hospital.	5230 Centre Avenue		Pittsburgh	PA	15232	412–623–6233	412–623–0051
UPMC Shadyside Hospital	5230 Centre Avenue		Pittsburgh	PA	15232	412–623–6233	412–623–6228
Upper Chesapeake Medical Center, Inc.	500 Upper Chesapeake Drive.		Bel Air	MD	21014	443–643–2449	443–643–4917
Upstate Medical University (SUNY).	750 East Adams Street		Syracuse	NY	13120	315–464–4232	315–464–7101
USC University Hospital	1500 San Pablo Street		Los Angeles	CA	90033	323–442–8479	
Utah Valley Regional Medical Center.	1034 S. 500 W		Provo	UT	84605	801–357–3613	
Val Verde Regional Medical Center.	801 Bedell Avenue		Del Rio	TX	78840	830–778–3656	830–778–3656
Valley Baptist Medical Center.	2101 Pease Street		Harlingen	TX	78550	956–389–1102	956–389–6763
Valley Care Medical Center	1111 East Stanley Boulevard.		Livermore	CA	94550	925–734–3335	925–416–3544
Valley Hospital Medical Center.	620 Shadow Lane		Las Vegas	NV	89106	702–894–5743	
Valley Medical Center	400 South 43rd Street		Renton	WA	98058	425.228.3440 X5965	
Valley Presbyterian Hospital	15107 Vanowen Street		Van Nuys	CA	91405	818–904–3742	818–902–5206
Valley Regional Medical Center.	Valley Regional Medical Center.	100A East Alton Gloor Building.	Brownsville	TX	78526	956–350–7327	956–350–7723
Valley View Medical Center	5330 S. Highway 95		Fort Mohave	AZ	86427	928 788 7248	928–788–7869
Vanderbilt Heart Institute	1215 21st Avenue	MCE 5th floor	Nashville	TN	37232	615–343 8231	
Vaughan Regional Medical Center.	1015 Medical Center Parkway.		Selma	AL	36701	334–418–4461	334–418–3588
VCU—Medical College of Virginia.	PO Box 980036		Richmond	VA	23298	804–828–9005	804–828–4528
Venice Regional Medical Center.	540 The Rialto		Venice	FL	34285	941–483–7713	941–483–7220
Verde Valley Medical Center.	269 South Candy Lane		Cotttonwood	AZ	86326	928–639–6486	928–639–6405
Verdugo Hills Hospital	1812 Verdugo Boulevard		Glendale	CA	91208	812–952–2243	
Via Christi Wichita Health Network.	929 N. St. Francis Street		Wichita	KS	67214	316–268–6763	
Ville Platte Medical Center	800 East Main Street		Ville Platte	LA	70586	337–363–9447	
Virginia Hospital Center	1701 N. George Mason Drive.		Arlington	VA	22205–3698	703–558–6678	703–558–6728
Virginia Mason Medical Center.	1100 Ninth Avenue	X3–CVL	Seattle	WA	98111	206–341–0530	206–223–6695
W. A. Foote Memorial Hospital.	Charles Anderson Building Level 4.	205 N. East Avenue.	Jackson	MI	49201	517–788–7880 x3450	517–780–7208
Wadley Regional Medica Center.	1000 Pine Street		Texarkana	TX	75501	903–798–7420	903–798–7428
WakeMed Cary Hospital	3128 Smoketree Court		Raleigh	NC	27604	919–350–2998	
WakeMed Raleigh Campus	3000 New Bern Avenue		Raleigh	NC	27610	919–350–6357	919–350–8972
Walker Regional Medical Center.	3400 Highway 78 E		Jasper	AL	35501	205–387–4009	
Washington Adventist Hospital.	7600 Carroll Avenue		Takoma Park	MD	20912	301 891–5901	301–891–6365
Washington County Hospital.	251 East Antietam Street		Hagerstown	MD	21740	301–790–8665	
Washington Hospital	2000 Mowry Avenue		Fremont	CA	94538	510–745–6504	
Washington Hospital Center	110 Irving Street NW Rm 5A14.		Washington	DC	20010	202–877–7687	202–877–2566
Washington Regional Medical Center.	1125 N College Avenue		Fayetteville	AR	72703–1994		
Waterbury Hospital	PO Box 2153		Waterbury	CT	06722–2153	203–575–5572	203–575–5575
Watsonville Community Hospital.	75 Nielson Street		Watsonville	CA	95076	831–761–5696	831–728–4758

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Waukesha Memorial Hospital.	725 American Avenue		Waukesha	WI	53188	262–928–2621	262–928–2775
Weatherford Regional Medical Center.	713 East Anderson Street		Weatherford	TX	76086	817–599–1845	817–599–1162
Weiss Memorial Hospital	4646 N. Marine Drive		Chicago	IL	60640	773–564–5917	773–564–5911
Wellmont Holston Valley Medical Center.	130 W Ravine Road		Kingsport	TN	37660	423–224–6529	423–224–6540
Wellstar Cobb Hospital	531 Roselane Street		Marietta	GA	30060	770–793–5218	677–331–6959
Wellstar Kennestone Hospital.	677 Church Street		Marietta	GA	30066	770–793–5218	678–331–6959
Wesley Medical Center	550 N. Hillside Street		Wichita	KS	67214	316–962–3230	
Wesley Medical Center	5001 Hardy Street		Hattiesburg	MS	39402	601–268–8526	
West Anaheim Medical Center.	3033 West Orange Avenue		Anaheim	CA	92084	714–229–4081	
West Florida Hospital	8383 Davis Highway		Pensacola	FL	32514	850–494–4028	850–494–4867
West Hills Hospital	7300 Medical Center Drive		West Hills	CA	91307	818–676–4106	818–676–4323
West Houston Medical Center.	12141Richmond Avenue		Houston	TX	77082	281–588–8248	281–596–5915
West Jefferson Medical Center.	1101 Medical Center Boulevard.		Marrero	LA	70072	504–349–1417	
West Suburban Medical Center.	3 Erie Court		Oak Park	Il	60302	708–763–2572	708–763–1591
West Valley Hospital	13677 W. McDowell Road		Goodyear	AZ	85338	623–882–1818	623–882–1510
West Virginia University Hospitals, Inc..	PO Box 8003	Medical Center Drive.	Morgantown	WV	26506–8003	304–598–6121	304–598–4277
Westchester County Medical Center.	95 Grasslands Road Suite 114.		Valhalla	NY	10595	914–493–5319	
Western Arizona Regional Medical Center.	2735 Silver Creek Road		Bullhead City	AZ	86442	928–763–2273	
Western Baptist Hospital	2501 Kentucky Avenue		Paducah	KY	42003	270–575–2300	270–575–8486
Western Medical Center Santa Ana.	1001 North Tustin Avenue		Santa Ana	CA	92705	714–953–2501	714–953–3481
Western Plains Medical Center.	3001 Avenue A		Dodge City	KS	67801	620–225–8402	
Westside Regional Medical Center.	8201 West Broward Boulevard.		Plantation	FL	33324	954–370–4445	954–577–2485
Wheaton Franciscan Healthcare—All Saints, Inc..	WFHC Clinical Data Management and Analysis.	5000 West Chambers, M229.	Milwaukee	WI	53210	414–447–2727	414–874–4386
Wheaton Franciscan Healthcare—St. Francis, Inc..	WFHC Clinical Data Management and Analysis.	5000 West Chambers, M229.	Milwaukee	WI	53210	414–447–2727	414–874–4386
Wheaton Franciscan Healthcare—St. Joseph, Inc..	WFH Clinical Data Management and Analysis.	5000 West Chambers, M229.	Milwaukee	WI	53210	414–447–2727	414–874–4386
Wheeling Hospital	1 Medical Park		Wheeling	WV	26003	304–243–3089	304–243–6400
White County Medical Center.	3214 E. Race Avenue		Searcy	AR	72143–4810	501–380–3102	501–380–3101
White Memorial Medical Center.	1720 Cesar E. Chavez Avenue.		Los Angeles	CA	90033	323–268–5000	323–881–8872
White River Medical Center	1710 Harrison Street		Batesville	AR	72501	870–262–6150	870–262–3170
William Beaumont Hospital	3601 West Thirteen Mile Road.		Royal Oak	MI	48073	248–898–4015	
William Beaumont Hospita—Troy.	44201 Dequindre Road		Troy	MI	48085	248–964–6874	248–964–6801
William W. Backus Hospital	326 Washington Street		Norwich	CT	06360	860–889–8331	860–425–3828
Willis-Knighton Medical Center.	2600 Greenwood Road		Shreveport	LA	71103	318–212–8576	318–212–4307
Wilson Memorial Hospital	915 West Michigan Street		Sidney	OH	45365	937–498–5524	937–498–5536
Wilson N. Jones Medical Center.	500 N Highland Avenue		Sherman	TX	75092	903–870–5516	903–870–5520
Winchester Medical Center Inc..	220 Campus Boulevard Suite 313.		Winchester	VA	22601	540–536–4750	540–536–6879
Winter Haven Hospital	20005 Avenue F Northeast		Winter Haven	FL	33881	863–293–1121 x3560	863–292–4123
Winthrop—University Hospital.	259 First Street		Mineola	Ny	11501	516–663–2476	516–663–2926
Wise Regional Health System.	609 Medical Center Drive		Decatur	TX	76234	940–627–5921 x3766	940–626–1387
Wishard Health Services Attn: A/P.	1001 W. 10th Street		Indianapolis	IN	46202	317–630–7203	
Woman's Christian Association Hospital.	207 Foote Avenue		Jamestown	NY	14701	716–664–8172	716–664–8241
Woodland Heights Medical Center.	505 S. John Redditt Drive		Lufkin	TX	75904	936–637–8520	936–637–8519
Wuesthoff Health System	110 Longwood Avenue		Rockledge	FL	32956–5002	321–636–2211 x1095	
Wyckoff Heights Medical Center.	374 Stockholm Street	Division of Cardiology—3rd Floor.	Brooklyn	NY	11237	718–486–4278	718–963–6396
Wyoming Medical Center	1233 East 2nd Street		Casper	WY	82601–2988	307–577–2548	307–577–5018
Wyoming Valley Health Care System.	575 North River Street		Wilkes-Barre	PA	18764	570–552–4415	570–552–4416

Facility name	Address 1	Address 2	City	State	Zip	Phone	Fax
Yakima Regional Medical Center/Cardiac Center.	110 S. 9th Avenue		Yakima	WA	98902	509–454–6508	
Yakima Valley Memorial Hospital.	2811 Tieton Drive		Yakima	WA	98902	509–249–5381	509–574–5800
Yale New Haven Hospital	20 York Street		New Haven	CT	06510		
Yavapai Regional Medical Center.	1003 Willow Creek Rd		Prescott	AZ	86301	928–771–5610	928–771–5615
York Hospital	15 Hospital Drive		York	ME	03909	207–351–3421	207–351–3427
York Hospital	1001 South George Street		York	PA	17405	717–851–4554	717–851–4206
Yuma Regional Medical Center.	2400 S. Avenue A		Yuma	AZ	85364	928–336–7055	928–336–7487

Addendum X—Active CMS Coverage-Related Guidance Documents [January Through March 2008]

On September 24, 2004, we published a notice in the **Federal Register** (69 FR 57325), in which we explained how we would develop coverage-related guidance documents. These guidance documents are required under section 731 of the MMA. In our notice, we committed to the public that, ''At regular intervals, we will update a list of all guidance documents in the **Federal Register**.''

Addendum X includes a list of active CMS guidance documents as of the ending date of the period covered by this notice. To obtain full-text copies of these documents, visit the CMS Coverage Web site at *http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcd_1*.

Document Name: Factors CMS Considers in Commissioning External Technology Assessments.

Date of Issuance: April 11, 2006.

Document Name: Factors CMS Considers in Opening a National Coverage Determination.

Date of Issuance: April 11, 2006.

Document Name: (Draft) Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee.

Date of Issuance: March 9, 2005.

Document Name: National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage With Evidence Development.

Date of Issuance: July 12, 2006.

Addendum XI—List of Special One-Time Notices Regarding National Coverage Provisions [January Through March 2008]

As medical technologies, the contexts under which they are delivered, and the health needs of Medicare beneficiaries grow increasingly complex, our national coverage determination (NCD) process must adapt to accommodate these complexities. As part of this adaptation, our national coverage decisions often include multi-faceted coverage determinations, which may place conditions on the patient populations eligible for coverage of a particular item or service, the providers who deliver a particular service, or the methods in which data are collected to supplement the delivery of the item or service (such as participation in a clinical trial).

We outline these conditions as we release new or revised NCDs. However, details surrounding these conditions may need to be shared with the public as ''one-time notices'' in the **Federal Register**. For example, we may require that a particular medical service may be delivered only in the context of a CMS-recognized clinical research study, which was not named in the NCD itself. We would then use Addendum XI of this notice, along with our coverage Web site at *http://www.cms.hhs.gov/coverage*, to provide the public with information about the clinical research study that it ultimately recognizes.

Addendum XI includes any additional information we may need to share about the conditions under which an NCD was issued as of the ending date of the period covered by this notice.

There were no Special One-Time Notices Regarding National Coverage Provisions published this quarter.

Addendum XII—National Oncologic PET Registry (NOPR)

In January 2005, we issued our decision memorandum on positron emission tomography (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the Registry. The following facilities have met the CMS's requirements for performing PET scans under National Coverage Determination CAG–00181N.

Facility name	Provider number	Date approved	State	Other information
Barnes-Jewish Hospital, Barnes-Jewish Plaza, Mailstop # 90–72–374, St. Louis, MO 63110.	E40080o	03/07/2006	MO.	
Duke University Medical Center PET Facility, Room 0402 Duke So., Durham, NC 27710.	34003	03/07/2006	NC	Yellow Zone Box 3949.
VCU Health System—Molecular Imaging Center, Dept of Nuclear Medicine—North Hospital 7th Floor, Richmond, VA 23298.	490032	03/07/2006	VA	1300 East Marshall—PO Box 980001.
Acadiana Oncologic Imaging, 2311 Kaliste Saloom, Lafayette, LA 70508.	5CA64	03/06/2006	LA.	
Adler Institute for Advanced Imaging, 261 Old York Road, Suite 106, Jenkintown, PA 19046.		03/07/2006	PA.	
Advanced Medical Imaging San Saba, 215 N San Saba, Suite 107, San Antonio, TX 78207.	00BC90	03/07/2006	TX.	
Advanced Medical Imaging Stone Oak, 540 Oak Centre, Suite 100, San Antonio, TX 78258.	00BC90	03/07/2006	TX.	
Advanced Radiological PET Imaging, PC, 2334 30th Avenue, Astoria, NY 11102.	05677	03/07/2006	NY	Lower Level.

Facility name	Provider number	Date approved	State	Other information
Akron Regional PET Scan, LLC, 3009 Smith Road, Suite 350, Akron, OH 44333.	AKID01691	03/07/2006	OH.	
American Radiology Services—Owings Mills, 21 Crossroads Drive, Suite 100, Owings Mills, MD 21117,.	434L	03/07/2006	MD.	
American Radiology Services—Bethesda, 6430 Rockledge Drive, Suite 100, Bethesda, MD 20817.	G00000	03/07/2006	MD.	
American Radiology Services—Waldorf, 3510 Old Washington Road, Suite 101, Waldorf, MD 20602.	435L	03/07/2006	MD.	
American Radiology Services—Columbia, 8820 Columbia Parkway 100, Columbia, MD 21045,.	434L	03/07/2006	MD.	
American Radiology Services—Frederick, 141 Thomas Johnson Drive, Suite 170, Frederick, MD 21702.	435L	03/07/2006	MD.	
American Radiology Services—Timonium, 2080 York Road, Suite 160, Timonium, MD 21093.	434L	03/07/2006	MD.	
Angel Williamson Imaging Center—Ft. Walton Beach, 1013–D Mar-Walt Drive, Ft. Walton Beach, FL 32547.	39953A	03/07/2006	FL.	
Angel Williamson Imaging Center—Pensacola, 5120 Bayou Boulevard, Suite 9, Pensacola, FL 32503.	39953	03/07/2006	FL.	
Edison Imaging Center, 3900 Park Avenue, Suite 107, Edison, NJ 08820.	AS008835	03/07/2006	NJ.	
Avon Medical Diagnostic Center, 1480 Center Road, Suite C, Avon, OH 44011.	MC4039571	03/07/2006	OH.	
Baltimore Imaging Centers, 3708 Mountain Road, Pasadena, MD 21122.	H476	03/07/2006	MD.	
Baptist Hospital PET/CT, 1000 West Moreno Street, Pensacola, FL 32501.	100093	03/07/2006	FL.	
Bethesda Health City, 2623 S Seacrest Boulevard, Boynton Beach, FL 33435.	40237	03/07/2006	FL.	
PET/CT Imaging at White Marsh, 9900 Franklin Square Drive, Suite D, Nottingham, MD 21236.	FMNX01	03/07/2006	MD.	
Biomedical Research Foundation PET Imaging Center, 1505 Kings Highway, Shreveport, LA 71103.	5D914	03/07/2006	LA.	
BodyScan of Louisville LLC, 807 Shelbyville Road, Suite 201, Louisville, KY 40222.	9372701	03/07/2006	KY.	
Bradley Regional PET Imaging, Cleveland, TN 37311	3373976	03/07/2006	TN	2305 Chambliss Ave NW.
PET Imaging Institute of NJ, 1608 Rte 88 West, Suite 302, Brick, NJ 08724.	070684	03/07/2006	NJ.	
Broward PET Imaging Center, LLC, 4850 W. Oakland Park Boulevard, Suite A, Fort Lauderdale, FL 33313.	E5709	03/07/2006	FL.	
Camelback Imaging, 15215 S. 48th Street, #110, Phoenix, AZ 85044,.	100488,	03/07/2006,	AZ.	
California Imaging and Treatment Center, 3000 Oak Road, #111, Walnut Creek, CA 95497.	ZZZ27175Z	03/07/2006	CA.	
Cancer Care Centers of Brevard, 1430 S Pine Street, Melbourne, FL 32901.	39835	03/07/2006	FL.	
Center for Medical Imaging—Florida Hospital, 1922 Salk Avenue, Tavares, FL 32778.	100057	03/07/2006	FL.	
Cancer Center of Colorado Springs, 320 E. Fontanero, Suite 200, Colorado Springs, CO 80907.	79804	03/07/2006	CO.	
Centro Sononuclear de Rio Piedras, 1028 Los Angeles Street, San Juan, PR 00926.	83910	03/07/2006	PR.	
Chattanooga Imaging East, 1710 Gunbarrel Road, Chattanooga, TN 37421.	3716643	03/07/2006	TN.	
Chester County PET Associates, 701 East Chester Marshall Street, West Chester, PA 19380.	085698	03/07/2006	PA.	
Cincinnati PET Scan, LLC—Kenwood, 7730 Montgomery Road, Suite 120, Cincinnati, OH 45236.	311754291	03/07/2006	OH.	
Cincinnati PET Scan, LLC Monfort Heights, 5575 Cheviot Road, Cincinnati, OH 45247.	311754291	03/07/2006	OH.	
Clinical PET of Hernando, 4003 Mariner Boulevard, Spring Hill, FL 34609.	L13228	03/07/2006	FL.	
Clinical PET of Citrus, 6140 W Corporate Oaks Drive, Crystal River, FL 34429.	U0121	03/07/2006	FL.	
Clinical PET of Lake City, 484 SW Commerce Drive, Suite 145, Lake City, FL 32025.	V2683	03/07/2006	FL.	
Clinical PET of Ocala, 3143 SW 32nd Avenue, Suite 100, Ocala, FL 34474.	E7179	03/07/2006	FL.	
Columbus Regional Hospital, 2400 East 17th Street, Columbus, IN 47201.	150112	03/07/2006	IN.	
Concord Imaging, 18802 Meisner Drive, San Antonio, TX 78258	00126Z	03/07/2006	TX.	
Dartmouth Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756.	.....	03/07/2006	NH.	

Facility name	Provider number	Date approved	State	Other information
Dedicated PET Imaging, 2315 Sunset Boulevard, Suite E, Steubenville, OH 43952.	01181	03/07/2006	OH.	
Diablo Valley Oncology & Hematology Medical Group, 3000 Oak Road, #111, Walnut Creek, CA 94597.	ZZZ26796Z	03/07/2006	CA.	
Diagnostic Imaging at Baywalk, 129 1st Avenue N, St. Petersburg, FL 33701.	00022	03/07/2006	FL.	
DMS Imaging, 2101 N. University Drive, Fargo, ND 58109	.....	03/07/2006	ND	PO Box 8070.
Doylestown PET Associates, 599 W. State Street, Doylestown, PA 18901.	059536	03/07/2006	PA	Suite 202.
East Bay Medical Oncology-Hematology Assoc., Inc, 3000 Oak Road, #111, Walnut Creek, CA 94597.	ZZZ267792	03/07/2006	CA.	
East River Medical Imaging, 519 East 72 Street, Suite 103, New York, NY 10021.	W11781	03/07/2006	NY.	
El Camino Imaging Center, 8020 Constitution Place NE, Albequerque, NM 87110.	237150	03/07/2006	NM.	
Elite Imaging, LLC, 2845 Aventura Boulevard, Suite 145, Aventura, FL 33180.	K3535	03/07/2006	FL.	
EPIC Imaging Center, 233 NE 102nd Avenue, Portland, OR 97220.	0000WCGNQ	03/07/2006	OR.	
Evergreen Radia, 11521 NE 128th Street, Kirkland, WA 98034	GAB39931	03/07/2006	WA.	
Excel Diagnostics Imaging Clinics, 9701 Richmond Avenue, Suite 122, Houston, TX 77042.	FTA109	03/07/2006	TX.	
First Imaging of the Carolinas, 30 Memorial Drive, Pinehurst, NC 29374.	2346997	03/07/2006	NC.	
Florida Hospital Advanced Nuclear Imaging PET, 328 Spruce Street, Orlando, FL 32804.	100007	03/07/2006	FL.	
Fort Jesse Imaging Center, LLC, 2200 Fort Jesse Road, Suite 120, Normal, IL 61761.	209824	03/07/2006	IL.	
Fox Chase Cancer Center, 333 Cotman Avenue, Philadelphia, PA 19111.	390196	03/07/2006	PA.	
Frederick Imaging Centers, 46B Thomas Johnson Drive, Frederick, MD 21702.	H476	03/07/2006	MD.	
Fusion Diagnostic Group, LLC, 1700 California Street, Suite 260, San Francisco, CA 94109.	00G366470	03/07/2006	CA.	
Fusion Imaging Institute, 2419 E. Commercial Boulevard, Suite 101, Ft. Lauderdale, FL 33308.	18281	03/07/2006	FL.	
Future Diagnostics Group, 254 N. Republic Avenue, Joliet, IL 60435.	200825	03/07/2006	IL.	
Greater Niagra PET, LLC, 1 Columbia Drive, Suite 3, Niagra Falls, NY 14305.	BA0213	03/07/2006	NY	Witmer Park Medical Center.
Hematology Oncology Associates of Baton Rouge, 4950 Essen Lane, Baton Rouge, LA 70809.	5C696	03/07/2006	LA.	
Gulf Coast Cancer & Diagnostic of Southeast, 12811 Beamer Road, Houston, TX 77089.	149949301	03/07/2006	TX.	
Henry Ford, Department of Radiology, 2799 W. Grand Boulevard, Detroit, MI 48202.	230053	03/07/2006	MI.	
High Point Regional Health System, 601 N. Elm Street, High Point, NC 27262.	3400040	03/07/2006	NC.	
Highlands Oncology Group, 3232 N. North Hills Boulevard, Fayetteville, AR 27203.	5B823	03/07/2006	AR.	
Holy Name Hospital, 718 Teaneck Road, Teaneck, NJ 07666 ...	310008	03/07/2006	NJ	PET/CT Center.
Holy Family Memorial Medical Center, PO Box 1450, Manitowoc, WI 54221.	520107	03/07/2006	WI	2300 Western Ave.
Hospital of Saint Raphael, 1450 Chapel Street, New Haven, CT 05611.	070001	03/07/2006	CT.	
San Patricio MRI & CT Center, 1508 Roosevelt Avenue, Suite 103, San Juan, PR 00920.	84997	03/07/2006	PR.	
Imaging Center of Hartford Hospital, 80 Seymour Street, PO Box 5037, Hartford, CT 06102.	070025	03/07/2006	CT.	
Indian Wells PET/CT Center, 74785 Highway 111, #101, Indian Wells, CA 92210.	1264523891	03/07/2006	CA.	
Imaging Technology Associates, 3800 Reservoir Road NW, Washington, DC 20007.	FDNCX1	03/07/2006	DC	Gorman 2043, PET Scan.
San Francisco Magnetic Resonance Center, 1180 Post Street, San Francisco, CA 94109.	ZZZ27498Z	03/07/2006	CA.	
Intermountain Medical Imaging, 2929 E Magic View Drive, Meridian, ID 83642.	82–05144–22	03/07/2006	ID.	
Jefferson Center City Imaging, 850 Walnut Street, Philadelphia, PA 19107.	66277	03/07/2006	PA.	
Kansas City Cancer Center—Kansas, 12200 W. 110th Street, Overland Park, KS 66210.	5650000D	03/07/2006	KS.	
Kansas City Cancer Center—Missouri, 4881 Goodview Circle, Lee's Summit, MO 66064.	5650000E	03/07/2006	MO.	

Facility name	Provider number	Date approved	State	Other information
Kreitchman PET Center, 180 Ft. Washington Avenue, HP3–315, New York, NY 10032.	WEM661	03/07/2006	NY.	
LakePointe PET, 10914 Hefner Pointe Drive, Suite 100, Oklahoma City, OK 73120.	700522143	03/07/2006	OK.	
Lakeshore PET Imaging, LLC, 4932 W 95th Street, Oak Lawn, IL 60453.	200108	03/07/2006	IL.	
Larchmont Imaging Associates, LLC, 210 Ark Road, Mt. Laurel, NJ 08054.	517216	03/07/2006	NJ.	
Las Cruces PET/CT Imaging, 1121 Mall Drive, Suite D, Las Cruces, NM 88011.	300521065	03/07/2006	NM.	
Lehigh Valley Diagnostic Imaging PET/CT, 1230 S. Cedar Crest Boulevard, Suite 104, Allentown, PA 18103.	563802	03/07/2006	PA.	
LifeScan Louisville, LLC, 4046 Dutchmans Lane, Louisville, KY 40207.	9365601	03/07/2006	KY.	
Limerick PET Associates, 420 W. Linfield-Trappe Road, Limerick, PA 19468.	075015	03/07/2006	PA	Suite 3400, Third Floor, Rear.
LifeScan Minnesota, 6525 France Avenue S, Suite 225, Edina, MN 55435.	470000014	03/07/2006	MN.	
Louisiana PET Imaging of Alexandra, LLC, 5419 A Jackson Street Exit, Alexandria, LA 71303.	5C743	03/07/2006	LA.	
LMR PET, 12600 Creekside Lane, Ft. Meyers, FL 33919	E5725	03/07/2006	FL.	
Louisiana PET Imaging of Lake Charles, LLC, 1750 Ryan Street, Lake Charles, LA 70601.	5C905	03/07/2006	LA.	
Insight Diagnostic Center—Forest Lane, 11617 N. Central Expressway, #132, Dallas, TX 75243.	FTA016	03/07/2006	TX.	
MDI of Thousand Oaks, 300 Lombard Street, Thousand Oaks, CA 91360.	W14186	03/07/2006	CA.	
Meadowbrook PET Associates, 1695 Huntington Pike, Meadowbrook, PA 19046.	064866	03/08/2006	PA.	
Medical Imaging of Baltimore, 6715 N. Charles Street, Baltimore, MD 21204.	258L	03/08/2006	MD.	
Metabolic Imaging of Laredo, 2344 Laguna Del Mar, Suites 5 & 6, Laredo, TX 78045.	FTN029	03/08/2006	TX.	
Methodist Hospital PET Imaging Center, 301 W. Huntington Drive, Suite 120, Arcadia, CA 91007.	9511643336	03/08/2006	CA.	
Metro Region PET Center at Chevy Chase, 5454 Wisconsin Avenue, Suite 810, Chevy Chase, MD 20815.	724811	03/08/2006	MD.	
Clinical PET of St. Charles County, 1475 Kisker Road, St. Charles, MO 63304.	000047047	03/08/2006	MO.	
Metro Region PET Center at Woodburn Nuclear Medicine, 3289 Woodburn Road, Annandale, VA 22003.	724811	03/08/2006	VA.	
Michiana Hematology-Oncology, PC, 100 Navarre Place, Suite 5550, South Bend, IN 46601.	216950	03/08/2006	IN.	
Michigan State University—Radiology, 184 Radiology Building, East Lansing, MI 48824.	OC36350	03/08/2006	MI.	
Clinical PET of West County, 450 N. New Ballas Road, Creve Coeur, MO 63141.	000093043	03/08/2006	MO.	
Modality Integration Services, Inc., 1854 SW Greenway Circle, West Linn, OR 97068.	.....	03/08/2006	OR.	
Molecular Imaging Center, 1733 Curie Drive, Suite 305, El Paso, TX 79912.	00315U	03/08/2006	TX.	
Molecular Imaging of Suburban Chicago, LLC, 908 N. Elm Street, Suite 110, Hinsdale, IL 60521.	212300	03/08/2006	IL.	
Montclair Road Imaging LLC, 924 Montclair Road, Suite 108, Birmingham, AL 35213.	000056277	03/08/2006	AL.	
Montefiore Medical Center, 1695A Eastchester Road, Bronx, NY 10461.	W06552	03/08/2006	NY.	
Neurodiagnostics, PSC, 1725 Harrodsburg Road, Suite 100, Lexington, KY 40504.	0406	03/08/2006	KY.	
New Century Imaging, 555 Kinderkamack Road, Oradel, NJ 07649.	085146	03/08/2006	NJ.	
Newport Diagnostic Center, 1605 Avocado Avenue, Newport Beach, CA 92660.	W13396	03/08/2006	CA.	
Next Generation Radiology PET/CT, 560 Northern Boulevard, Suite 111, Great Neck, NY 11021.	WR6091	03/08/2006	NY.	
North Valley MRI and CT, 1638 Esplanade, Chico, CA 95926 ...	ZZZ247802	03/08/2006	CA.	
Northwest Alabama Cancer Center Radiology Services, 302 W. Dr. Hicks Boulevard, Florence, AL 35630.	051552219	03/08/2006	AL.	
Northern Kentucky PET Scan, LLC, 651 Centre View Boulevard, Crestview Hills, KY 41017.	311754291	03/08/2006	KY.	
Northwest Cancer Center, 17323 Red Oak Drive, Houston, TX 77090.	00D29C	03/08/2006	TX.	
Northwestern Memorial Hospital, 251 East Huron Street, Chicago, IL 60611.	140281	03/08/2006	IL	Galter 8–113.

Facility name	Provider number	Date approved	State	Other information
Northern Shared Medical Services—Atlantic, IA, 1501 East Tenth Street, Atlantic, IA 50022.	I16068	03/08/2006	IA	Cass County Memorial Hospital.
Northern Shared Medical Services—Audubon, IA, 515 Pacific Street, Audubon, Iowa 50025.	I16068	03/08/2006	IA	Audobon County Memorial Hospital.
Northern Shared Medical Services—Beloit, KS, 400 West Eighth, Beloit, KS 67420.	130618	03/10/2006	KS	Mitchell County Hospital.
Northern Shared Medical Services—Bloomfield, IA, 507 North Madison Street, Bloomfield, IA 52537.	I16068	03/10/2006	KS	Davis County Hospital.
Northern Shared Medical Services—Carrollton, MO, 1502 North Jefferson, Carrollton, MO 64633.	000047013	03/10/2006	MO	Carroll County Memorial Hospital.
Northern Shared Medical Services—Centerville, IA, 1st St. Joseph Drive, Centerville, IA 52544.	I16068	03/10/2006	IA	Mercy Medical Center.
Northern Shared Medical Services—Carthage, IL, 160 S. Adams Street, Carthage, IL 62321.	208196	03/10/2006	IL	Memorial Hospital.
Northern Shared Medical Services—Clarinda, IA, 823 S. 17th Street, Clarinda, IA 51632.	I16068	03/10/2006	IA	Clarinda Regional Health Center.
Northern Shared Medical Services—Chanute, KS, 629 South Plummer, Chanute, KS 66720.	130618	03/10/2006	KS	Neosho Memorial Regional Medical Center.
Northern Shared Medical Services—Edwardsville, IL, 1121 University Drive, Edwardsville, IL 62025.	208196	03/10/2006	IL	Edwardsville Health Center.
Northern Shared Medical Services—El Dorado, AR, 700 West Grove Street, El Dorado, AR 71730.	5F168	03/10/2006	AR	Medical Center of South Arkansas.
Northern Shared Medical Services—Farmington, MO, 1212 Weber Road, Farmington, MO 63640.	000047013	03/10/2006	MO	Mineral Area Regional Medical Center.
Northern Shared Medical Services—Janesville, WI, 1321 Creston Park Drive, Janesville, WI 53545.	000092420	03/10/2006	WI	Janesville Occupational Health & Medical Center.
Northern Shared Medical Services—Hiawatha, KS, 300 Utah Street, Hiawatha, KS 66434.	130618	03/10/2006	KS	Hiawatha Community Hospital.
Northern Shared Medical Services—Keokuk, IA, 1600 Morgan Street, Keokuk, IA 52632.	I16068	03/10/2006	IA	Keokuk Area Hospital.
Northern Shared Medical Services—Macomb, IL, 525 East Grant Street, Macomb, IL 61455.	208196	03/10/2006	IL	McDonough District Hospital.
Northern Shared Medical Services—Mexico, MO, 620 East Monroe Street, Mexico, MO 65265.	000047013	03/10/2006	MO	Audrain Medical Center.
Northern Shared Medical Services—Moberly, MO, 1515 Union Avenue, Moberly, MO 65270.	000047013	03/10/2006	MO	Moberly Regional Medical Center.
Northern Shared Medical Services—Mountain Home, AR, 899 Burnett Drive, Mountain Home, AR 72653.	5F168	03/10/2006	AR	Cogburn Cancer Clinic.
Northern Shared Medical Services—Poplar Bluff, MO, 221 Physicians Park Drive, Poplar Bluff, MO 63901.	000047013	03/10/2006	MO	Poplar Bluff Medical Partners.
Northern Shared Medical Services—Perryville, MO, 434 North West Street, Perryville, MO 63775.	000047013	03/10/2006	MO	Perry County Memorial Hospital.
Northern Shared Medical Services—Rolla, MO, 1000 West Tenth Street, Rolla, MO 65401.	000047013	03/10/2006	MO	Phelps Co Regional Medical Center.
Northern Shared Medical Services—Virginia, MN, 901 Ninth Street North, Virginia, MN 55792.	470000057	03/10/2006	MN	Virginia Regional Medical Center.
Northern Shared Medical Services—Russellville, AR, 2504 West Main Street, Russellville, AR 72801.	5F168	03/10/2006	AR	Russellville Land Co.
Northern Shared Medical Services—West Plains, MO, 1100 Kentucky Avenue, West Plains, MO 65775.	000047013	03/10/2006	MO	Ozarks Medical Center.
Oakwood Hospital Medical Center, 18101 Oakwood Boulevard, Dearborn, MI 48124.	230020	03/10/2006	MI.	
Oakwood Southshore Medical Center, 5450 Fort Street, Trenton, MI 48183.	230176	03/10/2006	MI.	
Ocean Medical Imaging Center, 21 Stockton Drive, Toms River, NJ 08755.	158432	03/10/2006	NJ.	
Orange County Regional PET Center, LLC, 16300 Sand Canyon Avenue, Suite 103, Irvine, CA 92618.	TP018	03/10/2006	CA.	
Orange Advanced Imaging Center, 230 Main Street, #101, Orange, CA 92868.	TP016A	03/10/2006	CA.	
Pacific Coast Imaging—Irvine, 250 E Yale Loop, Suite A, Irvine, CA 92604.	WG87478B	03/10/2006	CA.	
Pacific Coast Imaging—Newport, 3300 West Coast Highway, Newport Beach, CA 92663.	WG87478	03/10/2006	CA.	
Pacific Imaging and Treatment Center, 5395 Ruffin Road, Suite 202, San Diego, CA 92123.	TP126	03/10/2006	CA.	
Palm Beach Cancer Institute, 1395 State Road 7, Suite 310, Wellington, FL 33414.	34754	03/10/2006	FL.	
Pennsylvania PET Associates, 800 Spruce Street, Philadelphia, PA 19107.	066282	03/10/2006	PA	Second Floor, Widener Building.
PET Center of Western NY, 127 North Street, Batavia, NY 14020.	187140	03/10/2006	NY.	

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Pet Imaging at CDR, 7600 N 15th Street, Suite 102, Phoenix, AZ 85020.	WCFDG	03/10/2006	AZ.	
PET Imaging at the Lake, 5000 Hennessy Boulevard, Baton Rouge, LA 70809.	5C868	03/10/2006	LA.	
PET Imaging Center at Harford County, 602 S Atwood Road, Suite 201, Bel Air, MD 21014.	FMN006	03/10/2006	MD.	
PET Imaging Institute of South Florida—East, 150 N 35th Avenue, 665, Hollywood, FL 33021.	E3783	03/10/2006	FL.	
PET Imaging Institute of South Florida—West, 603 N Flamingo Road, S–155, Pembroke Pines, FL 33028.	E3783	03/10/2006	FL.	
PET Scan Arizona—Peoria, 13460 N 94th Drive, Suite J1, Peoria, AZ 85381.	75400	03/10/2006	AZ.	
PET Scan Arizona—Phoenix, 6036 N 19th Avenue, Suite 305, Phoenix, AZ 85015.	66860	03/10/2006	AZ.	
PET/CT Diagnostic Medical Imaging, PC, 1200 Waters Place, Suite M108, Bronx, NY 10461.	W31091	03/10/2006	NY.	
Precision Imaging, 4416 East West Highway, Suite 410, Bethesda, MD 20814.	FMN005	03/10/2006	MD.	
Preferred PET Imaging of Kansas, LLC, 928 N. St. Francis Street, Wichita, KS 67214.	110693	03/10/2006	KS.	
Premium Diagnostics Center, 5319 Hoag Drive, Suite 130, Elyria, OH 44035.	ID01851	03/10/2006	OH.	
PET Center Ft. Worth, 800 W. Magnolia Avenue, Fort Worth, TX 76104.	0J062	03/10/2006	TX	Suite 100.
Radiology Associates, LLP, 6001 S. Staples Street, Corpus Christi, TX 78413.	00E816	03/10/2006	TX.	
S. Arlington Imaging Center, 4601 Matlock Road, Arlington, TX 76018.	0J062	03/10/2006	TX.	
Radiology Group Imaging Center, LLC, 1970 E. 53rd Street, Davenport, IA 52807.	16031	03/10/2006	IA.	
PET/CT Scan Center Pembroke, 11325 Pembroke Square, Suite 116, Waldorf, MD 20603.	521454775	03/10/2006	MD.	
New York MedScan, 751 Second Avenue, New York, NY 10017	978701	03/10/2006	NY.	
Rex Healthcare, 4420 Lake Boone Trail, Raleigh, NC 27607	340114	03/10/2006	NC.	
San Fernando Regional PET Center, 6855 Noble Avenue, Van Nuys, CA 91405.	TP078	03/10/2006	CA.	
PET/CT Imaging Center of Northwest Florida, 5149 North 9th Avenue, Suite 124, Pensacola, FL 32504.	U4696	03/10/2006	FL.	
Saint Joseph's Hospital—Nuclear Medicine, 611 St. Joseph Avenue, Marshfield, WI 54449.	520037	03/10/2006	WI.	
Shared PET Imaging, LLC—Brooklyn NY, 6300 Eight Avenue, Brooklyn, NY 11220.	97Z661	03/10/2006	NY.	
SC Cancer Specialists, 25 Hospital Center Boulevard #301, Hilton Head Island, SC 29926.	1285633289	03/10/2006	SC.	
Shared PET Imaging, LLC—Granger IN, 6901 N. Main Street, Granger, IN 46530.	232800	03/10/2006	IN.	
University Hospital—Cincinnati, Eden Avenue & Albert Sabin Way, Cincinnati, OH 45219.	.....	03/10/2006	OH.	
Shared PET Imaging, LLC—Marion OH, 1050 Delaware Avenue, Marion, OH 43302.	ID01511	03/10/2006	OH.	
Shared PET Imaging, LLC—Terre Haute IN, 3702 South Fourth Street, Terre Haute, IN 47802.	201320	03/10/2006	IN.	
South Jersey Radiology Associates, PA, 100 Carnie Boulevard, Suite B5, Voorhees, NJ 08043.	S0429966	03/10/2006	NJ.	
Southwest PET/CT Institute—Tucson, 3503 N. Campbell, Suite 155, Tucson, AZ 85719.	1396736922	03/10/2006	AZ.	
Southwest PET/CT Institute—Yuma, 1951 W. 25th Street, Suite G, Yuma, AZ 85364.	106077	03/10/2006	AZ.	
St. Francis Health Center, 1700 SW 7th Street, Topeka, KS 66606.	17–0016	03/10/2006	KS.	
Southwoods PET Scan, LLC, 250 Debartolo Place, Building B, Youngstown, OH 44512.	PCN05210036	03/10/2006	OH.	
St. Louis PET Centers, LLC, 12637 Olive Boulevard, Creve Coeur, MO 63376.	1861470734	03/10/2006	MO.	
St. Vincent's PET Center, LLC, 2660 10th Avenue S, POBI, Suite 104, Birmingham, AL 35205.	051555054	03/10/2006	AL.	
Sun Molecular Imaging—Peoria, 13090 N. 94th Drive, #103, Peoria, AZ 85381.	71585	03/10/2006	AZ.	
Sun Molecular Imaging—Sun City West, 13909 W Camino Del Sol, #101, Sun City West, AZ 85375.	71585	03/10/2006	AZ.	
Tarzana Advanced Imaging, 5536 Reseda Boulevard, Tarzana, CA 91356.	TP051A	03/10/2006	CA.	
The Methodist Hospital PET Center, 6565 Fannin Street, MBI–066, Houston, TX 77030.	450358	03/10/2006	TX.	

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Texarkana PET Imaging Institute, LP, 1929 Moores Lane, Texarkana, TX 75503.	FTN008	03/10/2006	TX.	
The PET/CT Center of North Florida, 5742 Booth Road, Jacksonville, FL 32207.	K7038P	03/10/2006	FL.	
The Washington Hospital, 155 Wilson Ave, Washington, PA 15301.	390042	03/10/2006	PA.	
The PET/CT Scanning Center, 235 18th Street, SE, Hickory, NC 28602.	2881788	03/10/2006	NC.	
Thompson Cancer Survival Center PET Imaging Center, 9711 Sherrill Boulevard, Knoxville, TN 37923.	3791106	03/10/2006	TN.	
Thunderbird MRI and PET Center, 6591 W. Thunderbird Road, Suite A–1, Glendale, AZ 85306.	79467	03/10/2006	AZ.	
Tower Imaging Roxsan, 465 N. Roxbury Drive, Suite 101, Beverly Hills, CA 90210.	TP114	03/10/2006	CA.	
Tower Hematology Oncology Medical Group, 9090 Wilshire Boulevard, Suite 200, Beverly Hills, CA 90211.	W11793	03/10/2006	CA.	
TRA Medical Imaging, 2202 S Cedar, Suite 200, Tacoma, WA 98405.	001055600	03/10/2006	WA.	
Trident PET of Fayette, 1275 Highway 54 West, Suite 102, Fayetteville, GA 30214.	47BBBJJ	03/10/2006	GA.	
Trident PET of Gwinnett, 545 Old Norcross Road, Lawrenceville, GA 30045.	47BBBGX	03/10/2006	GA	Suite 200.
Trident PET of Savannah, 7135 Hodgson Memorial Drive, Savannah, GA 31406.	47BBBKP	03/10/2006	GA	Suite 10A.
Tristan Associates, 4520 Union Deposit Road, Harrisburg, PA 17111.	112344	03/10/2006	PA.	
Union Square Diagnostic Imaging, 144 Fourth Avenue, New York, NY 10003.	WR7502	03/10/2006	NY.	
UCLA—Dept. of Molecular & Medical Pharmacology, 10833 Le Conte Avenue, Los Angeles, CA 90095.	HW13029	03/10/2006	CA	AR–115–CHS.
UCLA—Dept. of Molecular & Medical Pharmacology, 10833 Le Conte Avenue, Los Angeles, CA 90095.	HW13029	03/10/2006	CA	AR–115–CHS.
University Nuclear Medicine, Inc., 105 Parker Hall, Buffalo, NY 14214.	14414A	03/10/2006	NY	3435 Main St.
University Radiology Group, 75 Veronica Avenue, Suite 102, Somerset, NJ 08873.	425699	03/10/2006	NJ.	
Anne Arundel Medical Center, 2001 Medical Parkway, Annapolis, MD 21401.	210023	03/10/2006	MD.	
US Imaging Center Corp., LLC, 842 Sunset Lake Boulevard, Suite 301, Venice, FL 34292.	U0331	03/10/2006	FL.	
USC PET Imaging Science Center, 1510 San Pablo Street, Suite 350, Los Angeles, CA 90033.	W11874	03/10/2006	CA.	
Rolling Oaks Radiology, 415 Rolling Oak Drive, Suite 160, Thousand Oaks, CA 91361.	W10746	03/10/2006	CA.	
Vero Radiology Associates, Inc., 777 37th Street, Suite A–103, Vero Beach, FL 32960.	97445	03/10/2006	FL.	
Ventura Coast Imaging Center, 4601 Telephone Road, Suite 101, Ventura, CA 93003.	W11335	03/10/2006	CA.	
Washington Imaging Services, LLC, 1135–116th Avenue, NE, Bellevue, WA 98004.	GAB23386	03/10/2006	WA.	
Washington Hospital Center, 110 Irving Street, NW, Washington, DC 20010.	090011	03/10/2006	DC.	
Washoe Med Imaging Services at 75 Kirman, 75 Kirman Avenue, Reno, NV 89502.	WCHBB	03/10/2006	NV.	
Wesley Long Hospital—Moses Cone Health System, 501 North Elam Avenue, Greensboro, NC 27403.	34–0091	03/10/2006	NC.	
Westcoast Radiology, 36463 US Highway, 19 N., Palm Harbor, FL 34684.	E4187	03/10/2006	FL.	
Western Washington Oncology, 4525 3rd Avenue SE, Lacey, WA 98503.	1497749642	03/10/2006	WA.	
Windber Medical Center, 600 Somerset Avenue, Windber, PA 15963.	390112	03/10/2006	PA.	
Wyoming Valley PET Associates, 190 Welles Street, Forty Fort, PA 18704.	045012	03/10/2006	PA.	
Youngstown Regional PET Scan, 850 McKay Court, Youngstown, OH 44512.	Y0ID0174	03/10/2006	OH.	
X-RAY Associates at Santa Fe, 490 A West Zia Road, Suite 130, Santa Fe, NM 87505.	2258263	03/10/2006	NM.	
Sibley Memorial Hospital, 5255 Loughboro Road, NW, Washington, DC 20016.	090005	03/10/2006	DC.	
Lerman Diagnostic Imaging, 6511 Fort Hamilton Parkway, Brooklyn, NY 11215.	16H771	03/10/2006	NY.	
XRC Medical Imaging, 53940 Carmichael Drive, South Bend, IN 46635.	187390	03/10/2006	IN.	

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St. Luke's Hospital, 1026 A. Avenue N.E., Cedar Rapids, IA 52406–3026.	160045	03/10/2006	IA	P.O. Box 3026.
University Imaging at Science Park, 110 Science Parkway, Suite 100, Rochester, NY 14620.	16624A	03/10/2006	NY.	
Kadlec Medical Center/Nuclear Medicine Dept., 945 Goethals Street, Richland, WA 99352.	1972507580	03/10/2006	WA.	
Central Georgia PET, LLC, 1650 Hardmon, Macon, GA 31201	47BBBKC	03/10/2006	GA.	
PET/CT Imaging at Swedish Cancer Institute, 1221 Madison Street, First Floor, Seattle, WA 98104.	8857387	03/10/2006	WA.	
National PET Scan Duval, LLC, 425 North Lee Street, Jacksonville, FL 32204.	E7348	03/10/2006	FL.	
National PET Scan Pinellas, LLC, 805 Executive Center Drive W, St. Petersburg, FL 33702.	E7503	03/10/2006	FL.	
National PET Scan Dade, LLC, 7867 North Kendall Drive, Suite 121, Miami, FL 33156.	E5427	03/10/2006	FL.	
National PET Scan Broward, LLC, 6290 North Federal Highway, Fort Lauderdale, FL 33308.	E5432	03/10/2006	FL.	
Scottsdale Medical Imaging, Ltd., 7624 E. Indian School Road, Suite 109–1, Scottsdale, AZ 85251.	WCFKX	03/10/2006	AZ.	
Lakes Regional General Hospital, 80 Highland Street, Laconia, NH 03246.	300005	03/10/2006	NH.	
Northern California PET Imaging Center, 3195 Folsom Boulevard, Sacramento, CA 95816.	ZZZ15725Z	03/10/2006	CA.	
Northern California PET Imaging Center—Mobile, 3195 Folsom Boulevard, Sacramento, CA 95816.	ZZZ25157Z	03/10/2006	CA.	
Northern California PET Imaging Center—VAPA, 3801 Miranda Avenue, Palo Alto, CA 94304.	ZZZ21308Z	03/10/2006	CA.	
Advanced Medical Imaging, 3548 Route 9 South, Old Bridge, NJ 08857.	595865	03/10/2006	NJ.	
St. Vincent Infirmary Medical Center, PET/CT Center, 2 St. Vincent Circle, Little Rock, AR 72205–5499.	04–0007	03/10/2006	AR.	
Lincoln Trail Diagnostics, 1111 Woodland Drive, Elizabethtown, KY 42701.	470001408	03/10/2006	KY.	
LifeScan Imaging, 607 Clifty Street, Somerset, KY 42503	7614	03/10/2006	KY.	
St. John's Hospital Springfield Nuclear Medicine, 1235 E. Cherokee Street, Springfield, MO 65804.	26–0065	03/10/2006	MO.	
City of Hope, 1500 E. Duarte Road, Duarte, CA 91010	050146	03/10/2006	CA	Dept. of Nuclear Medicine.
Hackettstown Regional Medical Center, 651 Willow Grove Street, Hackettstown, NJ 07840.	310115	03/10/2006	NJ.	
Imaging Alliance—Nashville PET, LLC, 52 White Bridge Road, Nashville, TN 37205.	3791068	03/10/2006	TN.	
Molecular Imaging of Bradenton, 2301 60th Street, Court West, Suite A, Bradenton, FL 34209.	U1334	03/10/2006	FL.	
Molecular Imaging of Charlotte County, 4130 Tamiami Trail, Port Charlotte, FL 33952.	U1934	03/10/2006	FL.	
Imaging For Life, 3830 Bee Ridge Road, Suite A, Sarasota, FL 34233.	E6704	03/10/2006	FL.	
Seattle Nuclear Medicine/Ultrasound Associates, 1229 Madison Street, Suite 1050, Seattle, WA 98104.	G000158400	03/10/2006	WA.	
Columbus Circle Imaging, 1790 Broadway, 9th Floor, Yonkers, NY10704.	W00691	03/10/2006	NY.	
Bryn Mawr Imaging Center—PET, 100 Lancaster Avenue, Wynnewood, PA 19096.	473120	03/10/2006	PA.	
Beth Israel Deaconess Medical Center, 330 Brookline Avenue, Boston, MA 02215.	220086	03/10/2006	MA.	
Boca Raton Community Hospital, 800 Meadows Road, Boca Raton, FL 33486.	100168	03/10/2006	FL.	
Centro Tomograficio de PR, Inc., 1409 Ashford Avenue, San Juan, PR 00907.	0087834	03/10/2006	PR.	
Comprehensive Cancer Centers of Nevada, 3730 S. Easton, Las Vegas, NV 89109.	WCHCX	03/10/2006	NV.	
Grossman Imaging Center of CMH, 2151 E. Gonzales Road, Suite 101, Oxnard, CA 93036.	W17252	03/10/2006	CA.	
Cookeville Regional Medical Center, 142 W. 5th Street, Cookeville, TN 38501.	440059	03/10/2006	TN.	
Instituto Central de Diagnostico, Inc.,1er. Floor Oncologic Hospital, San Juan, PR 00928.	007835	03/10/2006	PR	PR Medical Center.
Mercy Medical Center—Cedar Rapids, 701 Tenth Street SE, Cedar Rapids, IA 52403.	16–0079	03/10/2006	IA.	
Midwest Radiologic Imaging—1144217241, 4087 Gateway Boulevard, Newburgh, IN 47630.	1144217241	03/10/2006	IN.	
Miami Valley Hospital, 1 Wyoming Street, Dayton, OH 45409 ...	360051	03/10/2006	OH.	

Facility name	Provider number	Date approved	State	Other information
Midwest Radiologic Imaging—214790, 4087 Gateway Boulevard, Newburgh, IN 47630.	214790	03/10/2006	IN.	
Midwest Regional PET/CT Center, 6001 S. Sharon Avenue, Suite #2, Sioux Falls, SD 57108.	41406	03/10/2006	SD.	
Mission Hospital, PET Center, 222 Asheland Avenue, Asheville, NC 28801.	3400002	03/10/2006	NC.	
Mobile Molecular Imaging, LLC, 100 Memorial Hospital Drive, Suite 1E, Mobile, AL 36608.	1003804345	03/10/2006	AL.	
Nebraska Health Imaging, 7819 Dodge Street, Omaha, NE 68114.	098975	03/13/2006	NE.	
Montgomery Metabolic & Memory Imaging Center, 7100 University Ct., Montgomery, AL 36117.	057554625	03/13/2006	AL.	
Orange County Diagnostic Radiology, Inc., 17150 Euclid Street, Suite 101, Fountain Valley, CA 92708.	TD057	03/13/2006	CA.	
Northwest PET Imaging, 265 N. Broadway, Portland, OR 97227	105512	03/13/2006	OR.	
Nevada Cancer Institute Medical Group, One Breakthrough Way, 10441 W. Twain Avenue, Las Vegas, NV 89135.	100505	03/13/2006	NV.	
Positron Emission Tomography Institute at Hampton, 5357 Henneman Drive, Norfolk, VA 23513.	FVN001	03/13/2006	VA.	
Positron Imaging Facility, 1311 Record Crossing Road, Mail Code 9140Dallas, TX 75235.	UT000F626	03/13/2006	TX.	
Premier Diagnostic Imaging, 10019 Forest Green Boulevard, Louisville, KY 40299.	9375201	03/13/2006	KY.	
Positron PET/CT of the Southern Tier, 169 Riverside Drive, Binghamton, NY 13905.	AA1047	03/13/2006	NY.	
Radiology Regional Center, PA, Inc.—Naples, 700 Goodlette Road, Naples, FL 34102.	77185	03/13/2006	FL.	
Somascan Plaza, Inc., Suite 405 Torre de Plaza Plaza Las Americas, San Juan, PR 00917.	0089178	03/13/2006	PR.	
Somascan, Inc., Jose Marti #56, San Juan, PR 00917	0082435	03/13/2006	PR.	
Southern Indiana Radiological Associates, 500 Landmark Avenue, Bloomington, IN 47403.	214160	03/13/2006	IN.	
Southern Illinois Cancer Center, 10286 Fleming Road, Carterville, IL 62918.	643740	03/13/2006	IL.	
South Nassau PET, One Healthy Way, Oceanside, NY 11572 ..	97z851	03/13/2003	NY.	
Southwest Diagnostic Center for Molecular Imaging, 8440 Walnut Hill Lane, Suite 100, Dallas, TX 75231.	FTN–015	03/13/2006	TX.	
St. Mary's Health Systems, 900 E. Oakhill Avenue, Knoxville, TN 37917.	440120	03/13/2006	TN.	
Tower Diagnostic Center, 4719 N. Habana Avenue, Tampa, FL 33614.	00169	03/13/2003	FL.	
Torrance Morial Medical Center, 3330 Lomita Boulevard, Torrance, CA 90505.	050351	03/13/2006	CA.	
University of Colorado Hospital (AOP), 1635 N. Ursula Street, Aurora, CO 80045.	06–0024	03/13/2006	CO.	
William Beaumont Hospital—Royal Oak, 3601 West 13 Mile Road, Royal Oak, MI 48073–6769.	23030	03/13/2006	MI.	
Esther Quijoy Catalya, M.D., 3000 Oak Road #111, Walnut Creek, CA 94597.	00A449120	03/13/2006	CA.	
Valley PET Institute, 311 S. Ham Lane, Lodi, CA 95242	00C283720	03/13/2006	CA.	
Dan Ben-Zeev, M.D., 3000 Oak Road #111, Walnut Creek, CA 94597.	00G129831	03/13/2006	CA.	
Midwest Center for Advanced Imaging, 1307 Macom Drive, Naperville, IL 60564.	L72461	03/13/2006	IL.	
Crittenton Hospital Medical Center, 1101 W. University Drive, Rochester, MI 48307.	230054	03/13/2006	MI.	
Medical Specialists of Palm Beaches, Inc., 5700 Lake Worth Road, Suite 204, Lake Worth, FL 33463.	33941A	03/13/2006	FL.	
PET Medical Imaging Center, 3264 North Evergreen Drive, Grand Rapids, MI 49525.	0P02650	03/13/2006	MI.	
Radiology Regional Center, PA, Inc.—RPET, 6100 Winkler Road, Suite A, Fort Myers, FL 33919.	77185	03/13/2006	FL.	
Good Samaritan Hospital, 520 S. 7th Street, Vincennes, IN 47591.	150042	03/13/2006	IN.	
Central Indiana Cancer Center, 6845 Rama Drive, Indianapolis, IN 46219.	065910	03/13/2006	IN.	
Decatur PET Imaging, 2774 W. Decatur Road, Decatur, GA 30033.	47BBBLP	03/13/2006	GA.	
Community Memorial Hospital, Medical Imaging, 855 S. Main Street, Oconto Falls, WI 54154.	00439MPN	03/13/2006	WI.	
Olympic Radiology, 2700 Clare Avenue, Bremerton, WA 98310	000242100	03/13/2006	WA.	
Capitol Imaging, 3161 L Street, Sacramento, CA 95816	1285615294	03/13/2006	CA.	
National Medical Imaging—Bryn Mawr, 574 W. Lancaster Avenue, Bryn Mawr, PA 19010.	024513	03/13/2006	PA.	

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National Medical Imaging—Langhorne, 2 Doublewoods Road, Suite BLanghorne, PA 19047.	024513	03/13/2006	PA.	
National Medical Imaging—Philadelphia, 1903–05 South Broad Street, Philadelphia, PA 19148.	024513	03/13/2006	PA.	
University of VA Health System, Radiology, 1215 Lee Street, Charlottesville, VA 22908.	490009	03/13/2006	VA.	
Florida Institute for Advanced Diagnostic Imaging, 9238 US 19, Port Richey, FL 34668.	59–3475930	03/13/2006	FL.	
Roseville PET & Nuclear Medicine Imaging, 2241 Douglas Boulevard #110, Roseville, CA 95661.	1194706689	03/13/2006	CA.	
Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10021.	330154	03/13/2006	NY.	
Northeast PET Imaging Center, 8400 Roosevelt Boulevard, Suite 208Philadelphia, PA 19152.	083723	03/13/2006	PA	Medical Arts Center at Parte Ridge.
UAMS PET Center, 4301 West Markham StreetLittle Rock, AR 72205.	50528	03/13/2006	AR.	
Joliet Oncology-Hematology Assoc., Ltd., 1600 W. Route 6, Morris, IL 60450.	205474	03/13/2006	IL.	
Saint Luke's Hospital, 4323 Wornall Road, Kansas City, MO 64111.	26–0138	03/13/2006	MO	AH Peet Center.
Mercy Medical Center, 1320 Mercy Drive, Canton, OH 44708 ...	360070	03/13/2006	OH.	
Dayton Medical Imaging Center, 7901 Schatz Pointe Drive, Dayton, OH 45459.	US1D00231	03/13/2006	OH.	
Community Radiology of Virginia, 2000 Leatherwood Lane, Bluefield, VA 24605.	FVA002	03/13/2006	VA.	
Bab Radiology—Huntington, 75 East Main Street, Huntington, NY 11743.	W1L612	03/13/2006	NY.	
Bab Radiology—Hauppauge, 521 Route 111, Suite 312, Hauppauge, NY 11788.	W1L601	03/13/2006	NY.	
Center for Diagnostic Imaging–37, 5775 Wayzata Boulevard #190, St. Louis Park, MN 55416.	470000037	03/13/2006	MN.	
Center for Diagnostic Imaging, 5775 Wayzata Boulevard, Suite 190, St. Louis Park, MN 55416.	C01307	03/13/2006	MN.	
Center for Diagnostic Imaging—Mendota Heights, 910 Sibley Memorial Highway, Mendota Heights, MN 55118.	470000038	03/13/2006	MN.	
Huntsville Hospital Imaging Center, 1963 Memorial Parkway, Huntsville, AL 35801.	010039	03/13/2006	AL.	
Long Beach PET Imaging Center, 2888 Long Beach Boulevard, Suite 110, Long Beach, CA 90806.	TG167	03/13/2006	CA.	
Highway Imaging Associates, LLP, 2095 Flatbush Avenue, Brooklyn, NY 11234.	W10671	03/13/2006	NY.	
St. Vincent Hospital, PO Box 13508, Green Bay, WI 54307	520075	03/13/2006	WI.	
Park South Imaging Center, 6215 21st Avenue, West #A, Bradenton, FL 34209.	E1858	03/13/2006	FL.	
Mary Bird Perkins Cancer Center, 4950 Essen Lane, Baton Rouge, LA 70809.	57290	03/13/2006	LA.	
Boston Diagnostic Imaging, 398 Altamonte Drive, Altamonte Springs, FL 32701.	E3510	03/13/2006	FL.	
Sioux Valley Hospital Medical Center, 1305 W. 18th Street, Sioux Falls, SD 57117.	430027	03/13/2000	SD.	
Indianapolis Regional PET Scan, LLC, 3830 Shore Drive, Indianapolis, IN 46254.	207260	03/13/2006	IN.	
St. Joseph's PET Center, 1 Mercy Lane, Suite 105, Hot Springs, AR 71913.	5C739	03/13/2006	AR.	
Hinsdale PET Scan, LLC, 812 Ogden Avenue, Westmont, IL 60559.	206271	03/13/2006	IL.	
Del Amo PET Imaging Center, 3531 Fashion Way, Torrance, CA 90501.	TP120	03/13/2006	CA.	
North Shore PET Imaging Center, 85 Herrick Street, Beverly, MA 1915.	327110	03/13/2006	MA	Beverly Hospital.
Robert D. Russo & Associates Radiology, PC, PO Box 6128, Bridgeport, CT 06606.	C02013	03/13/2006	CT.	
Advanced Medical Specialties, 9035 Sunset Drive, Suite 102, Miami, FL 33173.	K7806	05/03/2006	FL.	
Baptist M & S Imaging Center—Downtown, 215 E. Quincy Street #100, San Antonio, TX 78215.	FTA078	05/03/2006	TX.	
Community Cancer Center, 545 W. Umpqua Street, Roseburg, OR 97470.	R116571	05/03/2006	OR.	
Baptist M & S Imaging Center, 7888 Fredericksburg Road, San Antonio, TX 78228.	FTA078	05/03/2006	TX.	
Evanston Northwestern Healthcare—Highland Park, 757 Park Avenue West, Highland Park, IL 60035.	14–0010	05/03/2006	IL.	
Grenada Diagnostic Radiology, 1300 Sunset Drive, Suite U, Grenada, MS 38901.	470000034	05/03/2006	MS.	

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Huntsman Cancer Hospital, 2000 Circle of Hope, Suite 2121, Salt Lake City, UT 84112–5550.	460009	05/03/2006	UT.	
High Tech Medical Park, 11800 Southwest Highway, Palos Heights, IL 60463.	0703070	05/03/2006	IL.	
Cyrus Diagnostic Imaging, Inc., 165 Waymont Court, Lake Mary, FL 32746.	40586	05/03/2006	FL.	
Indiana Regional PET Imaging, 7891 Broadway, Suite A, Merrillville, IN 46410.	229400	05/03/2006	IN.	
Lancaster PET Imaging, 2100 Harrisburg Pike, Lancaster, PA 17601.	054504	05/03/2006	PA.	
James PET/CT Imaging Center, 236 Doan Hall, Columbus, OH 43210.	360242	05/03/2006	OH	410 W. 10th Ave.
Mary Lanning Memorial Hospital, 715 N. St. Joseph Avenue, Hastings, NE 68901.	280032	05/03/2006	NE.	
Maplewood Cancer Center—MOHPA, 1580 Beam Avenue, Maplewood, MN 55109.	C01828	05/03/2006	MN.	
Titusville Area Hospital, 406 W. Oak Street, Titusville, PA 16354.	390122	05/03/2006	PA.	
Memorial Hospital, 325 S. Belmont Street, York, PA 17403	390101	05/03/2006	PA.	
Mercy Regional Health Center, 1823 College Avenue, Manhattan, KS 66502.	17–0142	05/03/2006	KS.	
Northshore Regional PET Scan, LLC, 1464 Waukegan Road, Glenview, IL 60025.	206272	05/03/2006	IL.	
Northwest Indiana PET/CT Center, 1505 S. Calument Road, Suites 7 & 8, Chesterton, IN 46304.	229810	05/03/2006	AL.	
Parkway Ventures, Inc., 9000 Franklin Square Drive, Baltimore, MD 21237.	FMN002	05/03/2006	MD	Franklin Square Hospital.
PET Fusion Imaging, 3707 New Vision Drive, Fort Wayne, IN 46845.	190320	05/03/2006	IN.	
River Oaks Imaging & Diagnostics, PO Box 4346, Houston, TX 77210.	FTA059	05/03/2006	TX	Dept 848.
Regional PET Scan, LLC—Beachwood, 2000 Auburn Road, Beachwood, OH 44122.	REID02211	05/03/2006	OH.	
Regional PET Scan, LLC—Fairview, 20455 Lorain Road, Fairview Park, OH 44126.	REID02211	05/03/2006	OH.	
Regional PET Scan, LLC—Ridgepark, 7575 Northcliff Avenue, Brooklyn, OH 44144.	REID02211	05/03/2006	OH.	
Saint Francis Hospital, 114 Woodland Street, Hartford, CT 06105.	07–0002	05/03/2006	CT.	
St Nicholas Hospital, 3100 Superior Avenue, Sheboygan, WI 53081.	520044	05/03/2006	WI.	
Swedish Medical Center, 501 E. Hampton Avenue, Englewood, CO 80113.	060034	05/03/2006	CO.	
St Bernards PET Center, 225 E. Jackson Avenue, Jonesboro, AR 72401.	5C658	05/03/2006	AR.	
Toledo Regional PET Scan, LLC, 3442 Granite Circle, Toledo, OH 43617.	T0ID01881	05/03/2006	OH.	
University MRI, 3848 F.A.U. Boulevard, Suite 200, Boca Raton, FL 33431.	E1765	05/03/2006	FL.	
Tucson PET Imaging, 5355 E. Erickson Drive, Tucson, AZ 85712.	WCBBM	05/03/2006	AZ.	
Via Christi Oklahoma Regional Medical Center, 1900 N. 14th Street, Ponca City, OK 74601.	370006	05/03/2006	OK.	
Christian Hospital, 11133 Dunn Road, St Louis, MO 63136	260180	05/03/2006	MO.	
DRA Imaging PC, 1 Columbia Street, Poughkeepsie, NY 12601	W18691	05/03/2006	NY.	
Cleveland Clinic Star Imaging, 921 Jasonway Avenue, Columbus, OH 43214.	34–1932969	05/03/2006	OH.	
Norman PET Associates, LLC, 3750 W. Robinson Street, Suite 130, Norman, OK 73072.	900522224	05/03/2006	OK.	
Rhode Island PET Services—St. Josephs, 200 High Service Avenue, N Providence, RI 02904.	479003556	05/03/2006	RI.	
Rhode Island PET Services—South County Hospital, 100 Kenyon Avenue, Wakefield, RI 02879.	479003556	05/03/2006	RI.	
Rhode Island PET Services—Roger Williams, 825 Chalkstone Avenue, Providence, RI 02908.	479003556	05/03/2006	RI.	
Rhode Island PET Services—Landmark, 115 Cass Avenue, Woonsocket, RI 02895.	479003556	05/03/2006	RI.	
Forest City Diagnostic Imaging, 735 Perryville Road, Rockford, IL 61107.	546450	05/03/2006	IL	Lower Level 2.
New England Molecular Imaging—York, 15 Hospital Drive, York, ME 03909.	479003556	05/03/2006	ME.	
Pavilion Imaging, 750 Wellington Avenue, Grand Junction, CO 81502.	060023	05/03/2006	CO.	
Lifescan Chicago, 2242 W. Harrison Street, Chicago, IL 600612	470000014	05/03/2006	IL.	

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Southeast Medical Imaging, 300 Evergreen Drive, Suite 210, Glen Mills, PA 19342.	092801	05/03/2006	PA.	
The Western Pennsylvania Hospital, 4800 Friendship Avenue, Pittsburgh, PA 15224.	390090	05/03/2006	PA.	
Southtowns PET/CT, 550 Orchard Park Road, West Seneca, NY 14224.	14422A	05/03/2006	NY.	
Main Street Radiology—Bayside, 44–01 Francis Lewis Boulevard, Bayside, NY 11361.	04217	05/03/2006	NY.	
Main Street Radiology—Bayside, 44–01 Francis Lewis Boulevard, Bayside, NY 11361.	04217A	05/03/2006	NY.	
West VA University Center for Advanced Imaging, 1 Medical Center Drive, Morgantown, WV 26506.	9121131	05/03/2006	WV	PO Box 9236, Health Center South.
Twin Lakes Medical Specialist, PA, 228 Bucher Drive, Mountain Home, AR 72653.	5B019	05/03/2006	AR.	
Valley Metabolic Imaging, LLC, 6121 N Thesta Street, Fresno, CA 93710.	ZZZ23924Z	05/03/2006	CA	Suite 207.
Johnson City Medical Center, 400 North State of Franklin, Johnson City, TN 37642.	440063	05/03/2006	TN.	
St Louis University Hospital, 3665 Vista Avenue, St Louis, MO 63110.	000050109	05/03/2006	MO.	
Margaret R. Pardee Memorial Hospital, 800 North Justice Street, Hendersonville, NC 28791.	340017A	05/03/2006	NC.	
Valley Imaging Partnership1401 W. Merced Avenue #103, West Covina, CA 91790.	TP035	05/03/2006	CA.	
Sierra Imaging, 155 Calle Portal, Sierra Vista, AZ 85635	Z68496	05/03/2006	AZ.	
Aspirus Wausau Hospital, 333 Pine Ridge Boulevard, Wausau, WI 54401.	520030A	05/03/2006	WI.	
Cancer Care Northwest PET Center, 910 W 5th, Spokane, WA 99204.	1922072081	05/03/2006	WA	Suite 130.
PET/CT Imaging of North Texas, 2900 North I–35, Denton, TX 76201.	00088Y	05/03/2006	TX	Suite 119.
Loyola University Health System, 2160 S. First Avenue, Maywood, IL 60153.	140276	05/03/2006	IL.	
St. Elizabeth Medical Center, One Medical Village Drive, Edgewood, KY 41017.	180035	05/03/2006	KY.	
Cleveland Clinic, 9500 Euclid Ave, Cleveland, OH 44195	9925511	05/03/2006	OH.	
Ingalls Family Care Center, 6701 159th Street, Tinley Park, IL 60477.	14–0191	05/03/2006	IL.	
PET Fusion Center, 4204 Houma Boulevard, Metairie, LA 70006.	5CB31	05/03/2006	LA.	
United Regional Medical Center, 1001 McArthur Drive, Manchester, TN 37355.	440007	05/03/2006	TN.	
Joel Bernstein, MD, 5395 Ruffin Road, Suite 202, San Diego, CA 92123.	W18972	05/03/2006	CA.	
Hasnat Ahmed, MD, 5395 Ruffin Road, Suite 202, San Diego, CA 92123.	W18370	05/03/2006	CA.	
Meridian North Imaging Center, 12188 N. Meridian Street, Carmel, IN 46280.	026010	05/03/2006	IN	Suite 100.
Cancer Center Oncology Medical Group, 5395 Ruffin Road, Suite 202, San Diego, CA 92123.	W12245A	05/06/2006	CA.	
Firelands Regional Medical Center, 1101 Decatur Street, Sandusky, OH 44870.	360025	05/03/2006	OH.	
United Radiology—Greenbelt, PO Box 34979, West Bethesda, MD 20827.	FMN007	05/03/2006	MD.	
Richard Just, MD, 5395 Ruffin Road, Suite 202, San Diego, CA 92123.	W16197	05/03/2006	CA.	
Michael Kipper, MD, 5395 Ruffin Road, Suite 202, San Diego, CA 92123.	A24091	05/03/2006	CA.	
McLaren Regional Medical Center, 401 S. Ballenger Highway, Flint, MI 48532.	230141	05/03/2006	MI.	
United Radiology—Silver Spring, PO Box 34979, West Bethesda, MD 20827.	FMN007	05/03/2006	MD.	
United Radiology—Rockville, PO Box 34979, West Bethesda, MD 20827.	FMN007	05/03/2006	MD.	
St Mary's Health Center, 6420 Clayton Road, St Louis, MO 63117.	260091	05/03/2006	MO.	
Bay Regional Medical Center, 1900 Columbus Avenue, Bay City, MI 48708.	230041	05/03/2006	MI.	
Lapeer Regional Medical Center, 1375 N. Main Street, Lapeer, MI 48446.	230193	05/03/2006	MI.	
Scottsdale Medical Imaging, Ltd.—SW Diagnostics, 9003 E. Shea Boulevard, Scottsdale, AZ 85260.	1902896236	05/03/2006	AZ.	
Valley Medical Oncology Consultants, Inc., 3000 Oak Road #111, Walnut Creek, CA 94597.	ZZZ29659Z	05/03/2006	CA.	

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Northwest Community Hospital, 800 W Central Road, Arlington Heights, IL 60005.	36–2340313	05/03/2006	IL.	
PET Imaging of Dallas, 8333 Douglas Avenue, C–20,Dallas, TX 75225.	FTN017	05/03/2006	TX.	
PET Imaging of Dallas—Northeast, 1250 R Northwest Highway, Garland, TX 75041.	FTN028	05/03/2006	TX.	
St Joseph's Regional Medical Center, 703 Main Street, Paterson, NJ 07503.	310019	05/03/2006	NJ.	
PET Imaging of Houston, 2493–A South Braeswood, Houston, TX 77030.	FTN010	05/03/2006	TX.	
Goshen General Hospital, 200 High Park Avenue, Goshen, IN 46526.	150026	05/03/2006	IN.	
PET Imaging of ELMC, 8550 West 38th Avenue, Suite 102, Wheat Ridge, CO 80033.	800665	05/03/2006	CO.	
PET Imaging of Houston—Southeast, 6021 Fairmont Parkway, Suite 120, Pasadena, TX 77505.	FTN030	05/03/2006	TX.	
Peninsula Imaging, LLC, 560 Riverside Drive, Suite A104, Salisbury, MD 21801.	481L	05/03/2006	AL.	
Zwanger-Pesiri, 126 Hicksville Road, Massapequa, NY 11758 ..	W13931	05/03/2006	NY.	
Las Calinas PET Imaging, LLP, 1110 Cottonwood Lane, Irving, TX 75038.	FTN019	05/03/2006	TX	Suite 220.
Mt Carmel Regional Medical Center, 1102 East Centennial, Pittsburg, KS 66762.	014041	05/03/2006	KS.	
Iowa Blood & Cancer Care, PLC, 855 A. Avenue NE, Cedar Rapids, IA 52402.	I6672	05/03/2006	IA	Medical Office Plaza, LL4.
Hackensack University Medical Center, 30 Prospect Avenue, Hackensack, NJ 07601.	310001	05/03/2006	NJ.	
McLeod PET Imaging Center, 800 East Cheves Street, Florence, SC 29501.	570370242001	05/03/2006	SC	Suite 170.
St Alexius Medical Center, 900 E. Broadway Avenue, Bismarck, ND 58506.	35–0002	05/03/2006	ND	PO Box 5510.
Center for Diagnostic Imaging, 1295 Orange Avenue, Winter Park, FL 32789.	K0097	05/03/2006	FL.	
Charleston Radiologists, PA, 9313 Medical Plaza Drive, Charleston, SC 29406.	1709	05/03/2006	SC	Suite 302.
PET Imaging of Houston—West, 9525 Katy Freeway, Suite 102, Houston, TX 77024.	FTN023	05/03/2006	TX.	
University Hospitals of Cleveland, 11100 Euclid Avenue, Cleveland, OH 44106.	36–0137	05/03/2006	OH	Mailstop BSHB5056.
PET Imaging of Sugar Land, 17320 W Grand Parkway S., Suite A, Sugar Land, TX 77479.	FTN027	05/03/2006	TX.	
PET Imaging of Oklahoma City, 1000 N. Lincoln Boulevard, Suite 250, Oklahoma City, OK 73104.	800522283	05/03/2006	OK.	
PET Imaging of Tulsa, 6711 S. Yale, #104, Tulsa, OK 74136	400522320	05/03/2006	OK.	
PET Imaging of The Woodlands, 3091 College Park Drive, Suite 340, The Woodlands, TX 77384.	FTN021	05/03/2006	TX.	
Tarrant Diagnostic Imaging, 1121 8th Avenue, Fort Worth, TX 76104.	FTN012	05/03/2006	TX.	
Wyandot Memorial Hospital, 85 North Sandusky Avenue, Upper Sandusky, OH 43351.	361329	05/03/2006	OH.	
Oregon Health & Science University, 3181 SW Sam Jackson Park Road, Portland, OR 97229.	380009	05/03/2006	OR.	
Saint John's Health System, 2015 Jackson Street, Anderson, IN 46016.	150088	05/03/2006	IN.	
Hudson Valley PET Imaging, LLC, 160 North Midland Avenue, Nyack, NY 10960.	W1L903	05/03/2006	NY.	
Kingston Diagnostic Center, 167 Schwenk Drive, Kingston, NY 12401.	W1L921	05/03/2006	NY.	
Appleton Medical Center, 1818 N. Meade Street, Appleton, WI 54911.	520160	05/03/2006	WI.	
St. Elizabeth Health Center, 1044 Belmont Avenue, Youngstown, OH 44501.	360064	05/03/2006	OH.	
Sinai Hospital of Baltimore, 2401 West Belvedere Avenue, Baltimore, MD 21215.	210012	05/03/2006	MD.	
Associates in Radiology of Plattsburgh, NY, 762 Route 3, Suite 14, Plattsburgh, NY 12901.	33572A	05/03/2006	NY.	
Affiliated PET Systems—Rockville, 9711 Medical Center Drive, Rockville, MD 20850.	FDNX01	05/03/2006	MD.	
Lake Medical Imaging & Breast Center, 1400 US Highway 441 North, Suite 510, The Villages, FL 32159.	59–3522082	05/03/2006	FL.	
Affiliated PET Systems—Silver Spring, 1400 Forest Glen Road, Silver Spring, MD 20910.	FDNX01	05/03/2006	MD	Suite 430.
North Texas Clinical PET Institute, 3535 Worth Street, Suite 150, Dallas, TX 75246.	99R339	05/03/2006	TX.	

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Lake Imaging Center, 801 E. Dixie Avenue, Suite 104, Leesburg, FL 34748.	59–3635297	05/06/2006	FL.	
Edwards Comprehensive Cancer Center, 1400 Hal Greer Boulevard, Huntington, WV 25701.	510055	05/03/2006	WV.	
Allison Cancer Center, 301 North N Street, Midland, TX 79701	140414744	05/03/2006	TX.	
Clinical PET of Leesburg, 8525 US Highway 441, Leesburg, FL 34748.	E7179A	05/03/2006	FL.	
Greene Medical Imaging, PC, 159 Jefferson Heights, D–106, Catskill, NY 12414.	W25021	05/03/2006	NY.	
Caritas PET Imaging, LLC—Norwood Hosp, 70 Walnut Street, Foxboro, MA 02035.	32–7092	05/03/2006	MA	Caritas Norwood Hospital—Foxboro Campus.
Caritas PET Imaging, LLC—New England Medical Center, 750 Washington Street, Boston, MA 02111.	32–7092	05/03/2006	MA	Tufts—New England Medical Center.
Austin, Radiological Assn.—San Marcos, 1348 B Highway 123 South, San Marcos, TX 78666.	74–1597116	05/03/2006	TX.	
ARA Imaging—Rock Creek, 2120 N Mays, #220, Round Rock, TX 78664.	20–1651590	05/03/2006	TX.	
ARA Imaging—Southwood, 1701 W. Ben White Boulevard, #170, Austin, TX 78704.	20–1651590	05/03/2006	TX.	
Elkhart General Hospital, 600 East Boulevard, Elkhart, IN 46514.	15–0018	05/03/2006	IN.	
Austin, Radiological Assn.—Midtown, 1301 W. 38th Street, Suite 100, Austin, TX 78705.	74–1597116	05/03/2006	TX.	
Caritas PET Imaging, LLC—St. Elizabeth's, 736 Cambridge Street, Boston, MA 02135.	32–7092	05/03/2006	MA	St. Elizabeth's Medical Center.
Global PET Imaging, LLC, 1800 Hollister Drive, Suite G–10Libertyville, IL 60048.	309590	05/03/2006	IL	Grand Oaks Health Center.
Caritas PET Imaging, LLC—Carney Hospital, 2100 Dorchester Avenue, Dorchester, MA 02124.	32–7092	05/03/2006	MA	Caritas Carney Hospital.
Caritas PET Imaging, LLC—Milton Hospital, 92 Highland Street, Milton, MA 02186.	32–7092	05/03/2006	MA.	
Caritas PET Imaging, LLC—St. Anne's Hospital, 795 Middle Street, Fall River, MA 02721.	32–7087	05/03/2006	MA	St. Anne's Hospital.
Caritas PET Imaging, LLC—Good Samaritan, 235 North Pearl Street, Brockton, MA 02301.	32–7087	05/03/2006	MA	Caritas Good Samaritan Medical Center.
Panhandle PET Imaging, 6700 W. 9th Avenue, Amarillo, TX 79106.	TFN0007	05/03/2006	TX.	
PET Imaging of San Francisco, 1700 California Street, Suite 480, San Francisco, CA 94109.	ZZZ–223–782	05/03/2006	CA.	
PET/CT Imaging of Berkeley, 2855 Telegraph Avenue, Suite 100, Berkeley, CA 94705.	ZZZ–288–837	05/03/2006	CA.	
Western Maryland Health System—Sacred Heart Campus, 902 Seton Drive, Cumberland, MD 21502.	210027	05/03/2006	MD	Western Maryland Health System—Sacred Heart Campus.
Desert PET Imaging, LLC, 1180 N. Indian Cyn Drive, Palm Springs, CA 92262.	ZZZ28648Z	05/03/2006	CA.	
First PET of Stockton, 4744 Quail Lake Drive, Stockton, CA 95207.	00A484230	05/03/2006	CA.	
Utah Cancer Specialist, 3838 South 700 East, Salt Lake City, UT 84106.	57172	05/03/2006	UT	Suite 100.
Washington Radiology Associates, PC, 2121 K Street, NW, Washington, DC 20006.	WA409885	05/03/2006	DC	Suite T–120.
New Rochelle Radiology Associates, PC, 175 Memorial Highway, New Rochelle, NY 10801.	W05571	05/03/2006	NY.	
North Little Rock PET Associates, LLC, 3500 Springhill Drive, North Little Rock, AR 72117.	5F437	05/03/2006	AR	Suite 100.
Advanced Imaging Concepts, PL, 13063 Cortez Boulevard, Brooksville, FL 34613.	94774	05/03/2006	FL.	
Mansfield Imaging Center, 536 S. Trimble Road, Mansfield, OH 44906.	MAD10921	05/03/2006	OH.	
West Tennessee Imaging Center, 300 Coatsland Drive, Jackson, TN 38305.	44–0002	05/03/2006	TN.	
Imaging Center of North Central Indiana, Inc., 2201 W. Boulevard, Kokomo, IN 46902.	224110	05/03/2006	IN.	
University of Kansas Hospital, 3901 Rainbow Boulevard, Kansas City, KS 66160.	17–00040	05/03/2006	KS	Division of Nuclear Medicine.
PET Imaging of SWLA, LLC, 600 Bayou Pines East, Lake Charles, LA 70601.	5CK63	05/03/2006	LA	Suite A.
Community Imaging Partners of Frederick, 67 Thomas Johnson Drive, Frederick, MD 21702.	980M	05/03/2006	MD.	
Community Imaging Partners of Olney, 18111 Prince Phillip Drive #T–20, Olney, MD 20832.	409410	05/03/2006	MD	Community Imaging Partners.

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The West Clinic, PC, 100 N. Humphreys Boulevard, Memphis, TN 38120.	3704066	05/03/2006	TN.	
Imaging Central LLC, 7111 W. Central Avenue, Toledo, OH 43617.	IMID01641	05/03/2006	OH.	
Advanced Radiology—Dixon, 291 Stoner Avenue, Westminster, MD 21157.	527L	05/03/2006	MD.	
Advanced Radiology—Harford Imaging, 104 Plumtree Road, Bel Air, MD 21015.	527L	05/03/2006	MD	Suite 106.
Advanced Radiology—Cross Roads, 4801 Dorsey Hall Road, Ellicott City, MD 21042.	527L	05/03/2006	MD	Suite 101.
Advanced Radiology—PET Imaging of MD, 1700 Reisterstown Road, Baltimore, MD 21208.	527L	05/03/2006	MD	Suite 119.
Cancer & Blood Disease Center, 521 N. Lecanto Highway, Lecanto, FL 34461.	72840	05/03/2006	FL.	
Huntington Outpatient Imaging Center, Inc., 800 S. Fairmount Avenue, Pasadena, CA 91105.	W1575B	05/03/2006	CA	Suite 120.
Universal Imaging, Inc., 4600 Investment Drive, Troy, MI 48083	ON69130	05/03/2006	MI.	
Berger Health System, 1170 North Court Street, Circleville, OH 43113.	360710	05/03/2006	OH.	
Contemporary Imaging—Trenton, 1676 Fort Street, Trenton, MI 48183.	0P23200	05/03/2006	MI.	
South Tulsa PET, LLC, 7712 S. Yale Avenue, Tulsa, OK 74136	800522360	05/03/2006	OK	Ste 100.
Cancer Center of the Carolinas, 200 Andrews Street, Greenville, SC 29601.	6526	05/03/2006	SC	Suite 100.
OSF Saint Francis Medical Center, 530 NE Glen Oak Avenue, Peoria, IL 61637.	14–0067	05/03/2006	IL.	
Sacred Heart—St. Mary's Hospitals, Inc., 2251 Northshore Drive, Rhinelander, WI 54501.	1100700	05/03/2006	WI.	
Capital Region Radiation Therapy & Imaging, 3400 W. Truman Boulevard, Jefferson City, MO 65109.	260047	05/03/2006	MO	PO 150832.
University PET/CT Imaging, 19 Bradhurst Avenue, Hawthorne, NY 10532.	W2Y371	05/03/2006	NY	Suite 1200.
Aztech Radiology—Apache Trail, 1840 W. Apache Trail, Apache Junction, AZ 85222.	Z72398	05/03/2006	AZ.	
Aztech Radiology—Casa Grande, 1669 E McMurray Boulevard, Casa Grande, AZ 85222.	Z25341	05/03/2006	AZ.	
Missouri Cancer Associates, 105 N. Keene Street, Columbia, MO 65201.	000012700	05/03/2006	MO	Suite 100.
White River Medical Center, 1710 Harrison Street, Batesville, AR 72501.	040119	05/03/2006	AR.	
Englewood Hospital & Medical Center, 350 Engle Street, Englewood, NJ 07631.	310045	05/03/2006	NJ.	
Regional Imaging & Therapeutic Radiology Services, 360 Bard Avenue, Staten Island, NY 10310.	1023095445	05/03/2006	NY.	
Rocky Mountain Cancer Centers—South, 7951 E. Maplewood Avenue, Suite 300, Greenwood Village, CO 80111.	204508	05/03/2006	CO.	
Rocky Mountain Cancer Centers—North, 7951 E. Maplewood Avenue, Suite 300, Greenwood Village, CO 80111.	204508	05/03/2006	CO.	
Molecular Imaging of Hamilton County—Bethesda, 4197 Fulton Road NW, Suite C, Canton, OH 44718.	MOID01221	05/03/2006	OH.	
Molecular Imaging of Hamilton County—Good Sam, 4197 Fulton Road NW, Suite C, Canton, OH 44718.	MOID01221	05/03/2006	OH.	
Kettering Medical Center, 3535 Southern Boulevard, Kettering, OH 45429.	360079	05/03/2006	OH.	
St. Mary's Hospital, 5801 Bremo Road, Richmond, VA 23226 ...	540793767	05/03/2006	VA.	
Columbus Medical Institute of NY, 97–85 Queens Boulevard, Rego Park, NY 11374.	05679	05/03/2006	NY.	
Meadville Medical Center, 1034 Grove Street, Meadville, PA 16335.	39–0113	05/03/2006	PA.	
Chambersburg Hospital—Radiology, 112 North Seventh Street, Chambersburg, PA 17201.	390151	05/03/2006	PA.	
Oregon Advanced Imaging, 881 O'Hare Parkway, Medford, OR 97504.	R114546	05/03/2006	OR.	
Singing River Hospital, 2809 Denny Avenue, Pascagoula, MS 39581.	250040	05/03/2006	MS.	
East Texas Medical Center—Tyler, 1000 S. Beckham Avenue, Tyler, TX 75701.	4500833	05/03/2006	TX.	
Columbia, St. Mary's Hospital, 2025 E. Newport Avenue, Columbia Campus, Milwaukee, WI 53211.	520051	05/03/2006	WI.	
Sharon Regional Health System, 740 East State Street, Sharon, PA 16146.	390211	05/03/2006	PA.	
Northern Ohio Imaging Center, 1900 West River Road, Elyria, OH 44035.	36–0172	05/03/2006	OH.	

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Oxford Valley Diagnostic Center, 940 Town Center Drive, Langhorne, PA 19047.	232745550	05/03/2006	PA	Suite F50.
The Emory Clinic, 1365 Clifton Road, Building C, Room Court 048, Atlanta, GA 30322.	582030692	05/03/2006	GA.	
Alegent Health Bergan Mercy Medical Center, 7500 Mercy Road, Omaha, NE 68124.	280060	05/03/2006	NE.	
University Center Imaging, 1065 Delaware Avenue, Marion, OH 43302.	20–3873307	05/03/2006	OH.	
Elk Regional Health Center, 763 Johnsonburg Road, St Mary's, PA 15857.	39–0154	05/03/2006	PA.	
Health Park Hospital, 1636 Higdon Ferry Road, Hot Springs, AR 71913.	04–0142	05/03/2006	AR.	
Johnsonburg Health Center, 81 Clarion Road, Johnsonburg, PA 15845.	39–0104	05/03/2006	PA.	
Jane Phillips Medical Center, 3500 E. Frank Phillips Boulevard, Bartlesville, OK 74006.	370015	05/03/2006	OK.	
North Main Imaging Center, 7650 First Place, Suite B, Oakwood Village, OH 44146.	NEID01521	05/03/2006	OH.	
PET Imaging Center of Delaware County—DCMH, 501 North Lansdowne Avenue, Drexel Hill, PA 19026.	390081	05/03/2006	PA.	
NEO—PET CRC Imaging, 7650 First Place, Suite B, Oakwood Village, OH 44146.	NEID01521	05/03/2006	OH.	
PET Imaging Center of Delaware County—Springfield, 190 West Sproul Road, Springfield, PA 19064.	381080	05/03/2006	PA.	
Harper University Hospital, 3990 John R Street, Detroit, MI 48201.	230104	05/03/2006	MI.	
Sinai-Grace Hospital, 6071 W. Outer Drive, Detroit, MI 48235 ...	23–0024	05/03/2006	MI.	
Seattle Radiologists APC, 1229 Madison Street, Seattle, WA 98104.	G0001589600	05/03/2006	WA	#900.
Huron Valley—Sinai Hospital, 1 William Carl Drive, Commerce, MI 48382.	23–0277	05/03/2006	MI.	
East Memphis PET Imaging, 6005 Park Avenue, Memphis, TN 38119.	3374526	05/03/2006	TN	Suite 101B.
UPMC—PET Imaging Facility, 200 Lothrop Street, Pittsburgh, PA 15213.	390164	05/03/2006	PA	9th Floor, B-Wing PUH.
UPMC—PET Imaging Facility, 300 Halket Street, Pittsburgh, PA 15213.	390114	05/03/2006	PA.	
Rhode Island Hospital, 593 Eddy Street, Providence, RI 02903	05–025–8954	05/03/2006	RI.	
David C. Pratt Cancer Center, 607 South New Bulbs Road, St Louis, MO 63141.	260020	05/03/2006	MO.	
Lewistown Hospital, 400 Highland Avenue, Lewistown, PA 17044.	390048	05/03/2006	PA.	
Lawrence Memorial Hospital, 325 Maine Street, Lawrence, KS 66044.	170137	05/03/2006	KS.	
Jameson Hospital, 1211 Wilmington Avenue, New Castle, PA 16105.	39–0016	05/03/2006	PA.	
Diagnostic Clinic of Houston, 1200 Binz Street, Houston, TX 77004.	76–0203506	05/03/2006	TX.	
Arlington Heights Radiology Center, LLC, 121 South Wilke Road, Arlington Heights, IL 60005.	212301	05/03/2006	IL.	
Oregon Imaging Center, 1200 Hilyard Street, Eugene, OR 97401.	R0000WCPGH	05/03/2006	OR	#330.
Arlington Heights Radiology Center, LLC, 121 South Wilke Road, Arlington Heights, IL 60005.	212301	05/03/2006	IL.	
Indiana Univ Radiology Assoc PET Imaging Center, 950 W. Walnut Street, Room E124, Indianapolis, IN 46202.	959090	05/03/2006	IN.	
Morristown Memorial Hospital, 100 Madison Avenue, Morristown, NJ 07962.	310015	05/03/2006	NJ.	
Baton Rouge Radiology Group, 5422 Dijon Drive, Baton Rouge, LA 70808.	5B039	05/03/2006	LA.	
North Texas PET Imaging, 3720 South I–35E, Denton, TX 76210.	752131429	05/03/2006	TX.	
Children's Hospital of Michigan PET Center, 3901 Beaubien Street, Detroit, MI 48201.	23–3300	05/03/2006	MI.	
Winchester Medical Center, 1840 Amherst Street, Winchester, VA 22601.	490005	05/03/2006	VA.	
Decatur Health Imaging, LLC, 1123 16th Avenue SE, Decatur, AL 35601.	051555161	05/03/2006	AL.	
Health Imaging Services, LLC, 1760 Warnke Circle NE, Cullman, AL 35058.	051553273HEA	05/03/2006	AL.	
PET/CT Imaging of the Mainline, 21 Industrial Boulevard, Suite 103Paoli, PA 19301.	097715	05/03/2006	PA.	
PET Imaging of Brevard, 1430 Pine Street, Melbourne, FL 32901.	39254	05/03/2006	FL.	

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North Carolina Baptist Hospital, Medical Center Boulevard, Winston Salem, NC 27157.	34–0047	05/03/2006	NC.	
St Francis Hospital, 34515 9th Avenue S, Federal Way, WA 98003.	500108	05/03/2006	WA.	
Saint Barnabas Outpatient Center, 200 S. Orange Avenue, Livingston, NJ 07039.	440149	05/03/2006	NJ.	
PET/CT Imaging of Ramapa Radiology, 972 Route 45, Suite 106, Pomona, NY 10970.	W21711	05/03/2006	NY.	
Medical University of South Carolina PET/CT, 169 Ashley Avenue, Charleston, SC 29425.	420004	05/03/2006	SC.	
Akron General Medical Center, 300 Wabash Avenue, Akron, OH 44307.	36–0027	05/03/2006	OH.	
New England Molecular Imaging—Mercy Hospital, 144 State Road, Portland, ME 04103.	NE327075	05/03/2006	ME.	
New England Molecular Imaging—Penobscot Bay, 6 Glenn Cove Drive, Rockport, ME 04856.	NE327076	05/03/2006	ME.	
Center for Outpatient Services—St. Joseph, 3900 Hollywood Road, St. Joseph, MI 49085.	23–0021	05/03/2006	MI.	
New England Molecular Imaging—Central Maine, 12 High Street, Lewiston, ME 04240.	NE327076	05/03/2006	ME.	
Imaging Consultants, Inc.—Berkshire, 8 Conte Drive, Pittsfield, MA 01210.	327085	05/03/2006	MA.	
Imaging Consultants, Inc.—Boston Medical, 840 Harrison Avenue, Boston, MA 02118.	327083	05/03/2006	MA.	
Imaging Consultants, Inc.—Boston PET, One Brookline, Place, Brookline, MA 02445.	327083	05/03/2006	MA.	
Baptist Memorial Hospital PET Center, 6027 Walnut Grove Road, Memphis, TN 38120.	44–0048	05/03/2006	TN.	
Southern Oklahoma PET/CT Imaging, 701 E. Robinson Street, Norman, OK 73071.	90015477	05/03/2006	OK.	
Ann G. Fetters Diagnostic Imaging Center, 2151 N. Harbor Boulevard, Fullerton, CA 92835.	050168	05/03/2006	CA.	
Pitt County Memorial Hospital, 2100 Stantonsburg Road, Greenville, NC 27835.	56–0585243	05/03/2006	NC.	
Inland Imaging, LLC, 105 W. 8th Avenue, Spokane, WA 99202	AB01749	05/03/2006	WA	Suite 100C.
University of Chicago Hospitals, 5758 S. Maryland Avenue, Chicago, IL 60637.	140088	05/03/2006	IL	Room #0150.
Birch Medical Imaging Center, 20162 SW Birch Street, Newport Beach, CA 92660.	W19353	05/03/2006	CA.	
Tennessee Oncology PET Services, 2018 Murphy Avenue, Nashville, TN 37203.	3709319	05/03/2006	TN	Suite 200.
Tennessee PET Scan, 1020 N. Highland Avenue, Murfreesboro, TN 37130.	3791187	05/03/2006	TN	Suite A.
Texas Oncology—Harris Center HEB, 1615 Hospital Parkway, Bedford, TX 76022.	00R66C	05/03/2006	TX	Suite 300.
Greater Dayton Cancer Center, 3120 Governor's Place Boulevard, Kettering, OH 45409.	9295791	05/03/2006	OH.	
Martha Jefferson Hospital, 459 Locust Avenue, Charlottesville, VA 22902.	490077	05/03/2006	VA.	
Modern Diagnostic Imaging, 600 S. Dobson Road, Chandler, AZ 85224.	107628	05/03/2006	AZ	Suite B–16.
Christiana Care Nuclear Medicine/PET, 4755 Ogletown-Stanton Road, Newark, DE 19718.	080001	05/03/2006	DE.	
Advanced Imaging of Port Charlotte, LLC, 2625 Tamiami Trail, Port Charlotte, FL 33952.	K6802	05/03/2006	FL	Suite 1.
St. Joseph's Diagnostic Center—MLK, 3003 Martin Luther King, Jr. Boulevard, Tampa, FL 33067.	97779	05/03/2006	FL.	
South Carolina Oncology Associates, 166 Stoneridge Drive, Columbia, SC 29210.	6275	05/03/2006	SC.	
South Carolina Oncology Associates, 166 Stoneridge Drive, Columbia, SC 29210.	6276	05/03/2006	SC.	
Access Health Imaging, 5257 Highway 82, East, Lake Village, AR 71653.	5M809	05/03/2006	AR.	
PET/CT Services of Florida—Beverly Hills, 3404 N. Lecanto Highway, Beverly Hills, FL 34465.	V0103	05/03/2006	FL	Beverly Hills Medical Park.
PET/CT Services of Florida—Ocala, 1541 SW 1st Avenue, Ocala, FL 34474.	V0103	05/03/2006	FL	Suite 101B.
Blanchard Valley Regional Health Center, 145 W. Wallace Street, Findlay, OH 45840.	360095	05/03/2006	OH.	
Papastavros Associates Medical Imaging, 1701 Augustine Cut-Off, Wilmington, DE 19803.	1083615561	05/03/2006	DE.	
PET Imaging of Willowbrook, 13300 Hargrave Road, Houston, TX 77070.	FTN032	05/03/2006	TX	Suite 130.

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PET Imaging of Northern Colorado, 1915 Wilmington Drive, Ft Collins, CO 80528.	804621	05/03/2006	CO	Suite 101.
Temecula Valley Advanced Imaging, 25395 Hancock Avenue, Murrieta, CA 92592.	ZZZ–150752	05/03/2006	CA	Suite 110.
Saint Anthony Memorial Health Center, 301 West Homer Street, Michigan City, IN 46360.	A150015	05/03/2006	IN.	
Salina Regional Health Center, 400 S. Santa Fe Avenue, Salina, KS 67401.	170012	05/03/2006	KS	PO Box 5080.
Cancer Center of Kansas, 818 N. Emporia Street, Wichita, KS 67214.	110217	05/03/2006	KS	Suite 100.
Clinton Crossings Imaging, 995 Senator Keating Boulevard, Rochester, NY 14618.	14439A	05/03/2006	NY.	
NSMS—Shelby County, 4253 Argosy Court, Madison, WI 53714.	I16068	05/03/2006	WI.	
Verrazano Radiology, PC, 256A Mason Avenue, Staten Island, NY 10305.	200011201	05/03/2006	NY.	
Imaging Consultants, Inc.—Brockton Hospital, 680 Centre Street, Brockton, MA 02301.	327085	05/03/2006	MA.	
Imaging Consultants, Inc.—Cape Cod, 252 Long Pond Drive, Harwich, MA 02645.	327085	05/03/2006	MA	Fontain Medical Center.
Imaging Consultants Inc—Falmouth, 100 Ter Hewn Drive, Falmouth, MA 02540.	327085	05/03/2006	MA.	
Imaging Consultants, Inc.—Jordan, 275 Sandwich Street, Plymouth, MA 02360.	327085	05/03/2006	MA.	
Imaging Consultants, Inc.—Holyoke, 575 Beech Street, Holyoke, MA 01040.	327085	05/03/2006	MA.	
Imaging Consultants, Inc.—Mercy Medical, 271 Carew Street, Springfield, MA 01089.	327085	05/03/2006	MA.	
Imaging Consultants, Inc.—Lawrence Memorial, 170 Governors Avenue, Medford, MA 02155.	327083	05/03/2006	MA.	
Imaging Consultants, Inc.—Metro West, 115 Lincoln Street, Framingham, MA 01701.	327083	05/03/2006	MA.	
Imaging Consultants, Inc.—Milford, 14 Prospect Street, Milford, MA 01757.	327085	05/03/2006	MA.	
Imaging Consultants, Inc.—Quincy, 114 Whitwell Street, Quincy, MA 02196.	327083	05/03/2006	MA.	
Imaging Consultants, Inc.—Saints Memorial, 2 Hospital Drive, Lowell, MA 01852.	327083	05/03/2006	MA.	
Imaging Consultants, Inc.—Truesdale, 1030 Presidents Avenue, Fall River, MA 02720.	327085	05/03/2006	MA.	
Imaging Consultants, Inc.—Twin City, 76 Summer Street, Fitenburg, MA 01420.	N/A	05/03/2006	MA.	
Imaging Consultants, Inc.—Worcester, 20 Worcester Center Boulevard, Worcester, MA 01608.	327085	05/03/2006	MA.	
Sentara Mobile PET/CT—Careplex, 5900 Lake Wright Drive, Suite B, Norfolk, VA 23502.	250605	05/04/2006	VA.	
Sentara Mobile PET/CT—Lake Wright, 5900 Lake Wright Drive, Suite B, Norfolk, VA 23502.	250605	05/04/2006	VA.	
Sentara Mobile PET/CT—Princess Anne, 5900 Lake Wright Drive, Suite B, Norfolk, VA 23502.	250605	05/04/2006	VA.	
Sentara Mobile PET/CT—Williamsburg, 5900 Lake Wright Drive, Suite B, Norfolk, VA 23502.	250605	05/04/2006	VA.	
Memorial Hospital of South Bend, 615 N. Michigan Street, South Bend, IN 46601.	150058	05/04/2006	IN.	
NSMS—Belleville, IL, 4253 Argosy Court, Madison, WI 53714 ..	208196	05/04/2006	WI.	
NSMS—Flora, IL, 4253 Argosy Court, Madison, WI 53714	208196	05/04/2006	WI.	
NSMS—Breese, IL, 4253 Argosy Court, Madison, WI 53714	208196	05/04/2006	WI.	
SSM DePaul Health Center, 12303 DePaul Drive, St Louis, MO 63044.	260104	05/04/2006	MO.	
Lutheran Hospital, 7950 W. Jefferson Boulevard, Fort Wayne, IN 46804.	150017	05/11/2006	IN.	
Memorial MRI and Diagnostic, 1346 Campbell Road, Houston, TX 77055.	00941U	05/11/2006	TX.	
Shields Imaging of Eastern Mass, 55 Fogg Road, Weymouth, MA 2190.	327088	05/11/2006	MA.	
Baystate MRI and Imaging Center, 3300 Main Street, Springfield, MA 1107.	327039	05/11/2006	MA.	
Advanced Imaging Center, 16110 Jog Road, 200, Delray Beach, FL 33446.	U2049	05/11/2006	FL.	
UMASS Memorial MRI and Imaging Center, 214 Shrewsburg Street, Worcester, MA 1604.	327040	05/11/2006	MA.	
RCOA Imaging Services, 1108 Minnequa Avenue, Pueblo, CO 81004.	475748	05/11/2006	CO.	

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Adventist Health PET/CT—Hanford, 450 N. Greenfield Avenue, Hanford, CA 93230.	ZZZ318852	05/11/2006	CA.	
Adventist Health PET/CT—Feather River, 5974 Pertz Road, Paradise, CA 95969.	ZZZ318852	05/11/2006	CA.	
Adventist Health PET/CT—Sonora, 1000 Greenley Road, Sonora, CA 95370.	ZZZ318852	05/11/2006	CA.	
Sarasota Memorial PET, 5350 University Parkway, Sarasota, FL 34238.	U1775	05/11/2006	FL.	
Adventist Health PET/CT—Redbud, 18th Ave. at Highway 53, PO Box 6710, Clear Lake, CA 95422.	ZZZ318852	05/11/2006	CA.	
Adventist Health PET/CT—St. Helena, 10 Woodland Road, St. Helena, CA 94574.	ZZZ318852	05/11/2006	CA.	
Adventist Health PET/CT—Ukiah, 275 Hospital Drive, Ukiah, CA 95482.	ZZZ318852	05/11/2006	CA.	
Mease Outpatient Imaging, 1840 Mease Drive, Safety Harbor, FL 34685.	100265	05/11/2006	FL.	
Bardmoor Outpatient Center, 8787 Bryan Dairy Road, Largo, FL 33777.	00594C	05/11/2006	FL.	
Trinity Outpatient Center, 2102 Trinity Oaks Boulevard, New Port Richey, FL 34655.	00594D	05/11/2006	FL.	
Walnut Creek Imaging Center, 114 La Casa Via, #200, Walnut Creek, CA 94598.	ZZZ13902Z	05/11/2006	CA.	
Carlisle Imaging Center, 1240 S. Ft. Harrison, Clearwater, FL 33756.	594	05/11/2006	FL.	
Valley Radiology Imaging at Samaritan, 2581 Samaritan Drive, #100, San Jose, CA 95124.	ZZZ139851Z	05/11/2006	CA.	
Forest Hills PET Imaging, 102–02 Queens Boulevard, Forest Hills, NY 11375.	06998G	05/11/2006	NY.	
Roper LowCountry PET Imaging Center, 316 Calhoun Street, Charleston, SC 29401.	Q326280001	05/11/2006	SC.	
Premier PET Imaging of NJ, 119 Cherry Hill Road, Parsippany, NJ 07054.	68433	05/11/2006	NJ	Suite 100.
Methodist Medical Center of Illinois, 221 NE Glen Oak Avenue, Peoria, IL 61636.	370661223	05/11/2006	IL.	
Medical Imaging of Baltimore, 6715 N. Charles Street, Baltimore, MD 21204.	258L	05/12/2006	MD.	
Yagnesh Oza, MD, 4117 Velerous Memorial Drive, Mt Vernon, IL 62864.	212702	05/12/2006	IL.	
Moffitt Cancer Center, 12902 Magnolia Drive, Tampa, FL 33612	100271	05/12/2006	FL.	
PrimeMed Imaging, 5 Morgan Highway, Suite 7, Scranton, PA18505.	260	05/12/2006	PA	Morgan Medical Complex.
Rockville PET Imaging, PC, 119 North Park Avenue, Rockville Centre, NY 11570.	WTC601	05/12/2006	NY	Suite 101.
Porter Adventist Hospital, 2525 South Downing Street, Denver, CO 80210.	60064	05/12/2006	CO.	
Rapid City Regional Hospital Medical Imaging Services, 353 Fairmont Boulevard, Rapid City, SD 57701.	43007	05/12/2006	SD.	
Advanced Radiolgy Consultants, 56 Quarry Road, Trumbull, CT 06611.	C02747	05/12/2006	CT.	
Northeastern PA Imaging Center, 2601 Stafford Avenue, Scranton, PA 18505–0305.	475385	05/12/2006	PA	PO BOX 3305.
Billings MRI Center, 1041 North 29th Street, Billings, MT 59101–1075.	81030	05/12/2006	MT.	
Aurora St. Luke's Medical Center, 2900 W. Oklahoma Avenue, Milwaukee, WI 53215.	520138	05/12/2006	WI	Nuclear Medicine Department.
Memorial & St. Elizabeth's Healthcare Services, LLC, 4000 N. Illinois Lane, Swansea, IL 62226.	201339	05/12/2006	IL	PET/CT Imaging Center.
Palm Beach Cancer Institute—West Palm Beach, 1309 North Flagler Drive, West Palm Beach, FL 33401–2710.	34754	05/12/2006	FL.	
Overlook Hospital, 99 Beauvoir Avenue, Summit, NJ 07902	8772966189	05/12/2006	NJ.	
Ashland Bellefonte Cancer Center, 122 Saint Christopher Drive, Ashland, KY 41101.	2150	05/12/2006	KY.	
Bryn Mawr Imaging Center, 101 S. Bryn Mawr Avenue, Bryn Mawr, PA 19010.	473120	05/12/2006	PA.	
Oncology Alliance, 1055 N. Mayfair Road, Suite 100, Wauwatosa, WI 53220.	32836000	05/12/2006	WI.	
Shared PET Maimonides, 6300 Eighth Avenue, Brooklyn, NY 11220.	97Z661	05/12/2006	NY.	
Hoboken Radiology, LLC, 79 Hudson Street, Suite 100, Hoboken, NJ 07030.	80395	05/12/2006	NJ.	
Akron City Hospital, 525 E. Main Street, Akron, OH 44309	360020	05/12/2006	OH.	
Park Avenue Radiologists, PC, 525 E. Main Street, Rome, GA 30165.	W21771	05/12/2006	NY.	

Facility name	Provider number	Date approved	State	Other information
Comprehensive Blood & Cancer Center, 6501 Truxtun Avenue, Bakersfield, CA 93309.	zzz238732	05/12/2006	CA.	
Rome Imaging Center, 309 West 10th Street, Rome, GA 30165	GRP1221	05/12/2006	GA.	
Hawaii PET Imaging, 2230 Liliha Street, Honolulu, HI 96817	54537	05/12/2006	HI.	
Imaging Consultants, Inc. at Henry Heywood Hospital, 242 Green Street, Gardner, MA 01440.	327085	05/12/2006	MA.	
Imaging Consultants, Inc. at Nashoba Valley Medical Center, 200 Groton School Road, Ayer, MA 01432.	327085	05/12/2006	MA.	
Rhode Island PET Services at Memorial Hospital, 111 Brewster Street, Pawtucket, RI 2860.	479003556	05/12/2006	RI.	
Osceola Cancer Center, 737 W. Oak Street, Kissimmee, FL 34741.	1629034202	05/12/2006	FL.	
Valley Radiologists, Ltd.—Paseo II Office, 5605 W. Eugie Avenue, Suite 110, Glendale, AZ 85304.	1902896236	06/13/2006	AZ.	
Southeast GYN, Oncology PET, 5210 Belfort Road, Suite 130, Jacksonville, FL 32256.	45542	06/13/2006	FL.	
The Johns Hopkins PET Center, 600 N. Wolfe Street, Baltimore, MD 21287.	210009	06/13/2006	MD	Nelson Basement.
Maklansky, Grunter, Kurzban, Cohen, Zimmer, Hyman, 165 East 84th Street, New York, NY 10028.	W20393	06/13/2006	NY.	
Methodist Medical Center of Illinois, 112 Crescent Avenue, Peoria, IL 61636.	370661223	06/13/2006	IL.	
Phoebe Putney Memorial Hospital, 417 Third Avenue, PO Box 1828, Albany, GA 31702–1828.	110007	06/13/2006	GA.	
Eiber Radiology/PET Premier Imaging, 21 West 49th Street, Hialeah, FL 33012.	k3166	06/13/2006	FL.	
Botsford Hospital, 28050 Grand River Avenue, Farmington Hills, MI 48336.	230151	06/13/2006	MI.	
Middletown Regional Hospital, 105 McKnight Drive, Middletown, OH 45044.	360076	06/13/2006	OH.	
Waukesha Memorial Hospital, 725 American Avenue, Waukesha, WI 53188.	390910727	06/13/2006	WI.	
Battle Creek Health System, 300 North Avenue, Battle Creek, MI 49016.	230075	06/13/2006	MI.	
Orlando Regional Medical Center, 1414 Kuhl Avenue, Orlando, FL 32806.	100006	06/13/2006	FL.	
NorthEast Medical Center, 1065 NorthEast Gateway Court NE, Concord, NC 28025.	340001	06/13/2006	NC.	
Premier Medical Imaging, 7651 Stagers Loop, Delaware, OH 43015.	9912921	06/13/2006	OH.	
Advanced Radiolgy Consultants, 15 Corporate Drive, Trumbull, CT 6611.	C02747	06/13/2006	CT.	
Advance PET Imaging, 23 Technology Drive, East Setauket, NY 11733.	46a401	06/13/2006	NY.	
Premier PET Imaging of Wichita, 500 S. Main Street, Suite B, Wichita, KS 67202.	110682	06/13/2006	KS.	
Health Center Northwest, 320 Sunnyview Lane, Kalispell, MT 59901.	270087	06/13/2006	MT.	
Olympic Medical Center, 844 N. 5th Avenue, Sequim, WA 98382.	500072	06/13/2006	WA.	
Premier PET Imaging of Jacksonville, 5210 Belfort Road, Suite 130, Jacksonville, FL 32256.	K3166	06/13/2006	FL.	
PET/CT Imaging of San Jose, 2211 Moorpark Avenue, Suite 220, San Jose, CA 95128.	ZZZ19866Z	06/13/2006	CA.	
The Reading Hospital and Medical Center, 6th and Spruce Streets, West Reading, PA 19611.	390044	06/13/2006	PA.	
Julia Rackley Perry Memorial Hospital, 530 Park Avenue East, Princeton, IL 61356.	141337	06/13/2006	IL.	
Ashland Bellefonte Cancer Center, 122 Saint Christopher Drive, Ashland, KY 41101.	2150	06/13/2006	KY.	
Tower Imaging BBD, 14231 Bruce B Down Boulevard, Tampa, FL 33613.	169	06/13/2006	FL.	
VyMed Diagnostic Imaging Tampa, LLC, 10010 N. Dale Mabry, Suite 160, Tampa, FL 33618.	U4068	06/13/2006	FL.	
Texas Oncology Cancer Center Sugar Land, 1350 First Colony Boulevard, Sugar Land, TX 77479.	00073F	06/13/2006	TX.	
Samaritan North Health Center, 9000 N. Main Street, Dayton, OH 45415.	360052	06/13/2006	OH.	
The PET Center of Oxford, 1612 US Highway 78 East, Suite 102, Oxford, AL 36203.	51554888	06/13/2006	AL.	
Shared PET Mem Lighthouse, 6901 N. Main Street, Granger, IN 46530.	232800	06/13/2006	IN.	
Shared PET Hope Cancer Center, 3702 South Fourth Street, Terre Haute, IN 47802.	201320	06/13/2006	IN.	

Facility name	Provider number	Date approved	State	Other information
Athens Regional Medical Center, 1199 Prince Avenue, Athens, GA 30606.	110074	06/13/2006	GA.	
Muskogee PET & Nuclear Imaging, 3300 Chandler Road, Suite #106Muskogee, OK 74403.	400522529	06/13/2006	OK.	
Lubbock Imaging Center, 4011 19th Street, Lubbock, TX 79410	00027K	06/13/2006	TX.	
Memorial Medical Center, 701 N. First Street, Springfield, IL 62781.	140148	06/13/2006	IL.	
Hamamatsu/Queen's PET Imaging Center, 1301 Punchbowl Street, Honolulu, HI 96813.	.....	06/13/2006	HI.	
Aurora BayCare Medical Center, 2845 Greenbrier Road, Green Bay, WI 54308.	520193	06/13/2006	WI.	
Medical Center of Plano, 3901 W. 15th Street, Plano, TX 75002	450651	06/13/2006	TX.	
Carolinas Medical Center, 1000 Blythe Boulevard, Charlotte, NC 28203.	340113	06/13/2006	NC.	
Redwood Regional Medical Group d.b.a. Santa Rosa Radiology, 121 Sotoyome Street, Santa Rosa, CA 95405.	680344865	06/13/2006	CA.	
Boone Hospital Center, 1600 East Broadway, Columbia, MO 65201.	260068	06/13/2006	MO.	
River Radiology, 45 Pine Grove Avenue, Kingston, NY 12401 ...	W30681	06/13/2006	NY.	
University of Washington Medical Center, 1959 NE Pacific Street, Seattle, WA 98195.	142700	06/13/2006	WA.	
Mid American Imaging—Salem, 1987 E. 4th Street, Salem, OH 44460.	ID00804	06/13/2006	OH.	
Piedmont Medical Center, 222 S. Herlong Avenue, Rock Hill, SC 29732.	420002	06/13/2006	SC.	
Alliance Imaging—Sparks, 1311 South I Street, Fort Smith, AR 72817.	5F463	06/13/2006	AR.	
Radiology Imaging Associates, 1825 SE Tiffany Avenue, Suite 104, Port St. Lucie, FL 34952.	52	06/13/2006	FL.	
Mount Sinai Medical Center, One Gustave L. Levy Place, New York, NY 10029.	H23620	06/13/2006	NY.	
NSMS—Ottawa, IL, 4253 Argosy Court, Madison, WI 53714	208196	06/13/2006	WI.	
Center for Diagnostic Imaging, 1550 E. Chestnut Avenue, Vineland, NJ 08360.	53290	06/13/2006	NJ	Bldg 4, Suite A.
St. Mary Mercy Hospital—Livonia, 36475 Five Mile Road, Livonia, MI 48154.	230002	06/13/2006	MI.	
Harold Leever Regional Cancer, 1075 Chase Parkway, Waterbury, CT 06708.	470000025	06/13/2006	CT.	
Kentucky Metabolic Imaging, 2425 Regency Road, Suite B, Lexington, KY 40503.	9366001	06/13/2006	KY.	
Western Baptist Hospital, 2501 Kentucky Avenue, Paducah, KY 42001.	180104	06/13/2006	KY.	
St. Anthony Regional Hospital, 311 South Clark Street, Box 628, Carroll, IA 51401.	1720067127	06/13/2006	IA.	
Alliance Imaging—Sequoia Hospital, 170 Alameda De Las Pulgas, Redwood City, CA 94062.	ZZZ28890Z	06/13/2006	CA.	
Craven Regional Medical Center, 2000 Neuse Boulevard, New Bern, NC 28560.	340131	06/13/2006	NC.	
Alliance Imaging—Tri City Medical Center, 4002 Vista Way, Oceanside, CA 92056.	TG281C	06/13/2006	CA.	
Alliance Imaging—Yavapai, Del Webb Outpatient Center, Prescott Valley, AZ 86314.	76103	06/13/2006	AZ	3262 Windsong Drive.
Saint Vincent's Comprehensive Cancer Center, 325 West 15th Street, New York, NY 10011.	330290	06/13/2006	NY.	
Alliance Imaging—Southwest Medical Imaging, 3104 Stockton Hill Road, Kingman, AZ 86401.	76103	06/13/2006	AZ.	
Alliance Imaging—North Idaho Imaging, 700 Ironwood Drive, Coeur d'Alene, ID 93814.	1790291	06/13/2006	ID.	
Froedtert Hospital, 9200 W. Wisconsin Avenue, Milwaukee, WI 53226.	520177	06/13/2006	WI.	
Alliance Imaging—Flagstaff Medical Center, 1200 N. Beaver Street, Flagstaff, AZ 86001.	71855	06/13/2006	AZ.	
South Florida Oncology and Hematology Consultants, 4850 W. Oakland Park Boulevard, Lauderdale Lakes, FL 33313.	33873	06/13/2006	FL	Suite A.
Alliance Imaging—Sierra Vista, 300 El Camino Real, Sierra Vista, AZ 85635.	71855	06/13/2006	AZ.	
Alliance Imaging—St. Joseph Eureka, 2700 Dolbeer Street, Eureka, CA 95501.	zzz23046z	06/13/2006	CA.	
Alliance Imaging—Corvallis Clinic, 3680 NW Samaritan Drive, Corvallis, OR 97330.	132104	06/13/2006	OR.	
Bridgeport Hospital, 267 Grant Street, Bridgeport, CT 06610	70010	06/13/2006	CT.	
Valley Radiologists, Ltd.—Paseo II Office, 5605 W. Eugie Avenue, Glendale, AZ 85304.	1902896236	06/13/2006	AZ	Suite 110.

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Central Texas Medical Center, 1301 Wonder World Drive, San Marcos, TX 78666.	450272	06/13/2006	TX.	
Alliance Imaging—Verde Valley Medical Center, 269 S. Candy Lane, Cottonwood, AZ 86326.	76103	06/13/2006	AZ.	
Alliance Imaging—Union Hospital Cecil, 106 Bow Street, Elkton, MD 21821.	FMN008	06/13/2006	MD.	
St. Joseph Mercy Hospital—Ann Arbor, 5301 E. Huron River Road, Ann Arbor, MI 48106.	230156	06/13/2006	MI.	
Alliance Imaging—Navapache, 2200 E. Show Low Lake, Show Low, AZ 85901.	76103	06/13/2006	AZ.	
St. Clare Medical Center, 1710 Lafayette Road, Crawfordsville, IN 17933.	150022	06/13/2006	IN.	
Boynton Beach EFL, Imaging Center, LLC, 2300 S. Congress Avenue, Boynton Beach, FL 33426.	272376000	06/13/2006	FL	#105.
Aurora Medical Center Oshkosh, 855 N. Westhaven Drive, Oshkosh, WI 54904.	590198	06/13/2006	WI.	
Southeast GYN, Oncology PET, 5210 Belfort Road, Jacksonville, FL 32256.	45542	06/13/2006	FL	Suite 130.
Stockton MRI & Molecular Imaging Medical Center, 2320 N. California Street #2, Stockton, CA 95219.	ZZZ290872	06/13/2006	CA.	
South Texas Cancer Center, 2150 N. Expressway 83, Brownsville, TX 78521.	14041756	06/13/2006	TX.	
Southwest Cancer Care Medical Group, 5395 Ruffin Road, San Diego, CA 92123.	W4957B	06/13/2006	CA	#202.
Radiology Associates of Venice and Englewood, PA, 512–516 S. Nokomis Avenue, Venice, FL 34285.	99390	06/13/2006	FL.	
Langlade Memorial Hospital Oncology, 112 E. 5th Avenue, Antigo, WI 54409.	521350	06/13/2006	WI.	
RCOA Imaging Services, 305 South 5th Street, Enid, OK 73701	400522301	06/13/2006	OK.	
North Shore Hematology Oncology Associates, PC, 235 N. Belle Mead Road, East Setauket, NY 11733.	W04051	06/13/2006	NY.	
Providence Holy Cross Imaging Center, 26357 McBean Parkway, Suite 155, Santa Clarita, CA 91355.	TP129	06/13/2006	CA.	
Alaska Open Imaging Center, LLC, 6911 DeBarr Road, Anchorage, AK 99504.	K153149	06/13/2006	AK.	
Temecula Valley Nuclear Medicine, 25485 Medical Center Drive, Murrieta, CA 92562.	00A417170	06/13/2006	CA	Suite 102.
Hematology Oncology Assoc. of the Treasure Coast, 1801 SE Hillmoor Drive, Port Saint Lucie, FL 34952.	40806	06/13/2006	FL	Suite B–107 (Mobile).
The Center for Cancer and Blood Disorders, 800 W. Magnolia Avenue, Fort Worth, TX 76104.	00L79L	06/13/2006	TX.	
Alliance Imaging—South Coast Medical Cente, r31872 Pacific Coast Highway, Laguna Beach, CA 92651.	TG281B	06/13/2006	CA.	
The Medical Center at Bowling Green, 250 Park Street, Bowling Green, KY 42101.	180013	06/13/2006	KY	PET/CT Center.
Johns Hopkins Bayview Medical Center, 4940 Eastern Avenue, Baltimore, MD 21224.	210029	06/13/2006	MD	Imaging Department—Nuclear Medicine,
University of Michigan, Department of Radiology, 1500 E. Medical Center Drive, Ann Arbor, MI 48109.	230046	06/13/2006	MI	Box 0028, B1H418 University Hospital.
Carmichael Imaging, LLC, 4147 Carmichael Road, Montgomery, AL 36106.	51551742	06/13/2006	AL.	
Clearfield Hospital, 809 Turnpike Avenue, Clearfield, PA 16830	390052	06/13/2006	PA.	
Clinical Pet of Hernando, 4003 Mariner Boulevard, Spring Hill, FL 34609.	V2683	06/13/2006	FL.	
Booth Radiology, 105 Kings Way, W. Hurffville-Crosskeys Road, Sewell, NJ 08080.	39460	06/13/2006	NJ.	
Clinical PET of Zephyrhills, 38044 Daughtery Road, Zephyrhills, FL 33542.	E7179B	06/13/2006	FL.	
Radiology & Diagnostic Imaging, 2200 East Parrish Avenue, Owensboro, KY 42303.	3641	06/13/2006	KY	Building D.
Santa Monica Bay Physicians, 12524 W. Washington Boulevard, Los Angeles, CA 90066.	W14560	06/13/2006	CA.	
Missouri Baptist Medical Center, 3023 N. Ballas Road, St. Louis, MO 63141.	260108	06/13/2006	MO	Suite 150, Building D.
Radiology Associates of Tallahassee, PA, 1600 Phillips Road, Tallahassee, FL 32308.	60	06/13/2006	FL.	
Pacific Imaging—Oakland, 3200 Telegraph Avenue, Oakland, CA 94609.	1265480099	06/13/2006	CA.	
Medical Group of North County, 5395 Ruffin Road #202, San Diego, CA 92123.	W11609	06/13/2006	CA	#202.
Somerset Community Hospital, 225 South Center Avenue, Somerset, PA 15501.	390039	06/13/2006	PA.	
Elmbrook Memorial Hospital, 19333 W. North Avenue, Brookfield, WI 53045.	520170	06/13/2006	WI.	

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San Luis Diagnostic Medical Associates, 1100 Monterey Street, San Luis Obispo, CA 93401.	W14221	06/13/2006	CA	Suite 210.
Cancer Care Centers of S.Texas, PA (New Braunfels), 1448 Common Street, New Braunfels, TX 78130.	00U40Q	06/13/2006	TX.	
Cancer Care Centers of S.Texas, PA (San Antonio), 8109 Fredericksburg Road, San Antonio, TX 78229.	00U40Q	06/13/2006	TX.	
Cancer Care Centers of S.Texas, PA (Kerrville), 694 Hill Country Drive, Kerrville, TX 78028.	00U40Q	06/13/2006	TX.	
San Antonio Molecular Imaging SAMI, 9102 Floyd Curl Drive, San Antonio, TX 78240.	FTN025	06/13/2006	TX	Suite 193.
Pacific Medical Imaging and Oncology Center, Inc., 707 South Garfield Avenue, Alhambra, CA 91801.	W19267	06/13/2006	CA	Suite B–001.
Northern IL Cancer Treatment Center, 327 IL Route 2, Dixon, IL 61021.	210699	06/13/2006	IL.	
Cancer Care Center, 2210 Green Valley Road, New Albany, IN 47150.	243690	06/13/2006	IN	Suite 1.
Northeast Radiology, 3839 Danbury Road, Brewster, NY 10509	1134118607	06/13/2006	NY.	
New England PET Imaging System, 70 East Street, Methuen, MA1844.	M20762	06/13/2006	MA.	
Southeast Texas PET Imaging, 690 North 14th Street, Beaumont, TX 77702.	0004CC	06/13/2006	TX.	
Sun City West PET Scan, 14418 W. Meeker Boulevard, Sun City West, AZ 85374.	102496	06/13/2006	AZ	Suite 105.
Butler Memorial Hospital, 911 East Brady Street, Butler, PA 16001.	390168	06/13/2006	PA.	
Diagnos, Inc., d.b.a. Diagnos PET/CT Imaging, 2000 North Loop West, Houston, TX 77018.	ftnx11	06/13/2006	TX	Suite 100.
Alliance Imaging—Washington Hospital, 38950 Civic Center Drive, Fremont, CA 94538.	ZZZ28890Z	06/13/2006	CA.	
Providence Saint Joseph Hospital, 201 S. Buena Vista Street, Burbank, CA 91505.	50235	06/13/2006	CA	#125.
Alliance Imaging—Centinela Freeman, 333 Prairie Avenue, Inglewood, CA 90301.	TG281	06/13/2006	CA.	
Alliance Imaging—Corona Regional Hospital, 800 S. Main Street, Corona, CA 91720.	ZZZ23042Z	06/14/2006	CA.	
Alliance Imaging—St. Mary's Regional Medical Center, 235 W. 6th Street, Reno, NV 89503.	37860	06/14/2006	NV	235 W. 6th Street.
Alliance Imaging—Downey Regional Medical Center, 11500 Brookshire Avenue, Downey, CA 90241.	TG490	06/14/2006	CA.	
Alliance Imaging—Visalia Medical Clinic, 5400 W. Hillsdale Drive, Visalia, CA 93291.	ZZZ23046Z	06/14/2006	CA.	
Alliance Imaging—Anaheim Memorial Medical Center, 1111 W. La Palma Avenue, Anaheim, CA 92801.	TD017C	06/14/2006	CA	Anaheim Memorial Medical Center.
Glendale Diagnostic Imaging Network Medical Office, 403 South Glendale Avenue, Glendale, CA 91205.	W19100	06/14/2006	CA.	
Advanced Imaging at Baybrook, 11 Murray Street, Glens Falls, NY 12801.	33554a	06/14/2006	NY.	
Elizabethtown Hematology-Oncology PLC, 1107 Woodland Drive, Elizabethtown, KY 42701.	3638	06/14/2006	KY	Suite 105.
Northern Arizona Radiology, 77 W. Forest Avenue, Suite 101, Flagstaff, AZ 86001.	WCGJX	06/14/2006	AZ.	
Suburban Imaging—Coon Rapids, 8990 Springbrook Drive, Suite 140, Coon Rapids, MN 55433.	3087	06/14/2006	MN.	
Covenant Medical Center, 200 East Ridgeway Avenue, Waterloo, IA 50702.	421264647	06/14/2006	IA.	
Mayo Clinic Rochester, 10 3rd Avenue NW, Rochester, MN 55905.	1922074434	06/14/2006	MN	Charlton Building.
Thousand Oaks Diagnostic Imaging Center, 2180 Lynn Road, Thousand Oaks, CA 91360.	TP118	06/14/2006	CA.	
InnerVision Advanced Medical Imaging, 3801 Amelia Avenue, Lafayette, IN 47905.	167840	06/14/2006	IN.	
UT–M. D. Anderson Cancer Center—PET Facility, 1220 Holcombe Boulevard, Houston, TX 77030.	450076	06/14/2006	TX	ACB 6th Floor.
Emory University Hospital, 1364 Clifton Road, NE, Atlanta, GA 30322.	110010	06/14/2006	GA	Rm. E121 Nuclear Medicine/PET.
Glendale MRI Institute, 624 S. Central Avenue, Glendale, CA 91204.	HW9951	06/14/2006	CA.	
Princeton Radiology, 9 Centre Drive, Jamesburg, NJ 08831	526492	06/14/2006	NJ.	
Caromont Imaging Services, 620 Summit Crossing Place, Gastonia, NC 28054.	340032	06/14/2006	NC	Suite 106.
North Central Imaging, 155 Sonterra Boulevard, Suite 100, San Antonio, TX 78258.	00867N	06/14/2006	TX.	
Robert L. B. Tobin Diagnostic Imaging Center, 7979 Wurzbach Drive, Suite U113, San Antonio, TX 78229.	00867N	06/14/2006	TX.	

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Edwards Comprehensive Cancer Center, 1400 Hal Greer Boulevard, Huntington, WV 25701.	510055	06/14/2006	WV.	
Home Hospital GLHS, 2400 South Street, Lafayette, IN 47904	150109	06/14/2006	IN.	
St. Luke's North PET, 153 Brodhead Road, Bethlehem, PA 18017.	390049	06/14/2006	PA.	
Alamance Regional Medical Center, 1240 Huffman Mill Road, Burlington, NC 27216–0202.	340070	06/14/2006	NC	PO Box 202.
Verrazano Radiology, 256 Mason Avenue, Staten Island, NY 10305.	1698	06/14/2006	NY.	
Total Imaging Sun City, 3862 Sun City Center, Sun City Center, FL 33571.	U4840	06/14/2006	FL.	
Ortonville Area Health Services, 450 Eastvold Avenue, Ortonville, MN 56278.	241342	06/14/2006	MN.	
Merle West Medical Center, 2865 Daggett Avenue, Klamath Falls, OR 97601.	380050	06/14/2006	OR.	
Elite Imaging, LLC, 2845 Aventura Boulevard, Aventura, FL 33180.	K3535	06/14/2006	FL	Suite 145.
St. Mary Centralia, 400 N. Pleasant Avenue, Centralia, IL 62801.	140034	06/14/2006	IL.	
North Texas Regional Cancer Center, 3705 W. 15th Street, Plano, TX 75075.	00543K	06/14/2006	TX.	
Centegra Health System, 4201 Medical Center Drive, McHenry, IL 60050.	140116	06/14/2006	IL.	
Boston Diagnostic Imaging, 398 East Altamonte Drive, Altamonte Springs, FL 32701.	77022	06/14/2006	FL.	
William W. Backus Hospital, 326 Washington Street, Norwich, CT 06360.	70024	06/14/2006	CT.	
NSMS—Sparta, IL, 4253 Argosy Court, Madison, WI 53714	208196	06/14/2006	WI.	
LaPorte Hospital & Healthcare Services, 1007 Lincolnway, LaPorte, IN 46350.	150006	06/14/2006	IN.	
Skagit Valley Hospital, 1415 E. Kincaid Street, Mt.Vernon, WA 98273.	500003	06/14/2006	WA.	
Alliance Imaging—Fairfield Hospital, 303 NW 11th Street, Fairfield, IL 62837.	213393	06/14/2006	IL.	
Anderson Hospital, 6800 State Route 162, Maryville, IL 62062 ..	212761	06/14/2006	IL.	
Alliance Imaging—Dean, 1313 Fish Hatchery Road, Madison, WI 53715.	92170	06/14/2006	WI.	
Alliance Imaging—Research, 2316 E. Meyer Boulevard, Kansas City, MO 64112.	9004263A	06/14/2006	MO.	
Alliance Imaging—St. Joseph, 1000 Carondelet Drive, Kansas City, MO 64114.	9004263A	06/14/2006	MO.	
Beebe Health Campus, d.b.a. Beebe Medical Center, 18941 John J. Williams Highway, Rehoboth, DE 19971.	80007	06/14/2006	DE.	
Medical Outsourcing Services, LLC, 1200 Maple Road, Joliet, IL 60432.	211223	06/14/2006	IL.	
Silver Spring Radiology, 10801 Lockwood Drive, Silver Spring, MD 20901.	FDX009	06/14/2006	MD	STE 170.
New England PET of Greater Lowell, 295 Varnum Avenue, Lowell, MA 01854.	327080	06/14/2006	MA.	
Stanford University, 900A Blake Wilbur Drive, Stanford, CA 94305.	50441	06/14/2006	CA.	
Medical Outsourcing, Services, LLC, 3333 W. DeYoung Street, Marion, IL 62959.	211224	06/14/2006	IL.	
Medical Outsourcing Services, LLC, 1700 Clinton Street, Muskegon, MI 49443.	230066	06/14/2006	MI.	
Medical Outsourcing Services, LLC, 1001 Bellefontaine Avenue, Lima, OH 45807.	MEID02391	06/14/2006	OH.	
Golf Diagnostic Imaging Center, 9680 Golf Road, Des Plaines, IL 60016.	378810	06/14/2006	IL.	
Medical Outsourcing Services, LLC, 2816 South Ellis Avenue, Chicago, IL 60616.	211222	06/14/2006	IL.	
Medical Outsourcing Services, LLC, 1100 E. Norris Drive, Ottawa, IL 61350.	211224	06/14/2006	IL.	
Medical Outsourcing Services, LLC, 111 E. Spring Street, Streator, IL 61364.	211224	06/14/2006	IL.	
Mansfield Imaging Center, 536 S. Trimble Road, Mansfield, OH 44906.	MAD10921	06/14/2006	OH	Suite A.
Manhattan Diagnostic Radiology, 400 East 66th Street, New York, NY 10021.	W23211	06/14/2006	NY.	
Riverside Walter Reed Hospital, 7519 Hospital Drive, Gloucester, VA 23061.	490130	06/14/2006	VA.	
Good Shepherd Hospital, 450 West Highway 22, Barrington, IL 60010.	140291	06/14/2006	IL.	

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Alliance Imaging—Presbyterian Intercomm Hospital, 12401 Washington Boulevard, Whittier, CA 90602.	TG281A	06/14/2006	CA	Presbyterian Intercommunity Hospital.
Altru Hospital, 1200 S. Columbia Road, Grand Forks, ND 58201	350019	06/14/2006	ND.	
Mid American Imaging—Union Hospital, 659 Boulevard Street, Dover, OH 44622.	ID00805	06/14/2006	OH.	
Gundersen Clinic, 1900 South Avenue, Lacrosse, WI 54601	34217	06/14/2006	WI.	
University of Minnesota Medical Center, Fairview, 500 Harvard Street, SE, Box 292, Minneapolis, MN 55455.	C02390	06/14/2006	MN.	
The Christ Hospital, 2139 Auburn Avenue, Cincinnati, OH 45219.	360163	06/14/2006	OH.	
West Michigan Cancer Center, 200 N. Park Street, Kalamazoo, MI 49007.	0N66660	06/14/2006	MI.	
Cyrus Diagnostic Imaging, Inc., 165 Waymont Court, Lake Mary, FL 32746.	40586	06/14/2006	FL.	
Cancer Centers of Florida, 1561 West Fairbanks Avenue, Winter Park, FL 32789.	K1833	06/14/2006	FL.	
Cedars-Sinai Medical Center, 8700 Beverly Boulevard, Adler-Nail PET Center, Los Angeles, CA 90048.	951644600	06/14/2006	CA	S. Mark Taper Foundation Imaging Center.
Cancer Centers of Florida, 52 West Gore Street, Orlando, FL 32806.	K1833	06/14/2006	FL.	
Cancer Centers of Florida, 1111 Blackwood Avenue, Ocoee, FL 34761.	K1833	06/14/2006	FL.	
Mt. Clemens Regional Medical Center, 1000 Harrington Street, Mt. Clemens, MI 48043.	230227	06/14/2006	MI.	
Truxtun Radiology Medical Group, LP, 1818 16th Street, Bakersfield, CA 93301.	ZZZ25213Z	06/14/2006	CA.	
Medical Outsourcing Services, LLC, 1515 North Madison Avenue, Anderson, IN 46011.	223260	06/14/2006	IN.	
Medical Outsourcing Services, LLC, 1215 Franciscan Drive, Litchfield, IL 62056.	211224	06/14/2006	IL.	
Piedmont Medical Center, 1968 Peachtree Road, NW, Atlanta, GA 30305.	110083	06/14/2006	GA.	
Medical Outsourcing Services, LLC, 1400 West Park Street, Urbana, IL 61801.	211224	06/14/2006	IL.	
Central Indiana PET, LLC, 8301 Harcourt Road, Suite 100, Indianapolis, IN 46260.	201930	06/14/2006	IN.	
Medical Outsourcing Services, LLC, 812 North Logan Avenue, Danville, IL 61832.	211224	06/14/2006	IL.	
Queens Medical Imaging, PC, 69–15 Austin Street, Forest Hills, NY 11375.	1023011285	06/14/2006	NY.	
NYOH PET/CT Imaging, 43 New Scotland Avenue, Albany, NY 12208.	56917A	06/14/2006	NY.	
Conroe Regional Medical Center, 504 Medical Center Boulevard, Conroe, TX 77304.	450222	06/14/2006	TX.	
Northeast Georgia Health System, Inc., Northeast Georgia Medical Center, 743 Spring Street, Gainesville, GA 30501.	110029	06/14/2006	GA.	
Texas Oncology, PA—Mckinney, 4510 Medical Center Drive, Mckinney, TX 75069.	00543K	06/14/2006	TX	#215.
Medical Outsourcing Services, LLC, 7150 Clearwater Drive, Indianapolis, IN 46256.	223260	06/14/2006	IN.	
Medical Outsourcing Services, LLC, 1402 East County Line Road, Indianapolis, IN 46227.	223260	06/14/2006	IN.	
Texas Cancer Center—Sherman, 2800 Highway 75 North, Sherman, TX 75090.	00543K	06/14/2006	TX.	
Medical Outsourcing Services, LLC, 120 Ralston Avenue, Defiance, OH 43512.	MEID02391	06/14/2006	OH.	
Medical Outsourcing Services, LLC, 2400 N. Rockton Avenue, Rockford, IL 61103.	211224	06/14/2006	IL.	
Arlington Cancer Center, 906 W. Randol Mill Road, Arlington, TX 76012.	00LK20	06/14/2006	TX.	
Jupiter Medical Center, 2055 Military Trail, Jupiter, FL 33458	100253	06/14/2006	FL.	
Cheyenne Radiology Group and MRI, PC, 2003 Bluegrass Circle, Cheyenne, WY 82009.	W309142	06/14/2006	WY.	
Hunterdon Imaging, PA, 2100 Wescott Drive, MRI, Suite, Flemington, NJ 08822.	714119	06/14/2006	NJ.	
Medical Outsourcing Services, LLC, 200 Berteau Avenue, Elmhurst, IL 60126.	211223	06/14/2006	IL.	
Magnolia Regional Center, 611 Alcorn Drive, Corinth, MS 38834.	250009	06/14/2006	MS.	
Monroe Clinic, 515 22nd Avenue, Monroe, WI 53566	520028	06/14/2006	WI.	
Jupiter Hematology-Oncology Associates, 345 Jupiter Lakes Boulevard, Jupiter, FL 33458.	34922	06/14/2006	FL	Ste.100.
Southwest Regional Cancer Center, 901 West 38th Street, Austin, TX 78705.	0080BY	06/14/2006	TX.	

Facility name	Provider number	Date approved	State	Other information
Positron Imaging Of Austin, 6101 Balcones Drive, Austin, TX 78731.	00538K	06/14/2006	TX.	
Southern Ocean County Hospital, 1140 Route 72 West, Manahawkin, NJ 08050.	310113	06/14/2006	NJ	Radiology.
Medical Outsourcing Services, LLC, 9830 S. Ridgeland Road, Chicago Ridge, IL 60145.	211222	06/14/2006	IL.	
Medical Outsourcing Services, LLC, 430 West Votaw Street, Portland, IN 47374.	223260	06/14/2006	IN.	
Saint Agnes Medical Center, 1303 E. Herndon Avenue, Fresno, CA 93720.	50093	06/14/2006	CA.	
Central Physicians Imaging, 100 Southland Drive, Lexington, KY 40503.	9375001	06/14/2006	KY	Suite B.
NEA Medical Center, 3024 Stadium Boulevard, Jonesboro, AR 72401.	1386699353	06/14/2006	AR.	
Northgate Medical Imaging, LLC, 807 Northgate Boulevard, New Albany, IN 47150.	1205894235	06/14/2006	IN.	
Ball Memorial Hospital, 2401 University Avenue, Muncie, IN 47303.	150089	06/14/2006	IN.	
The MRI Center, 5200 Harroun Road, Sylvania, OH 43560	360074	06/14/2006	OH	Flower Hospital.
St. Joseph Regional Health Center, 2801 Franciscan Drive, Bryan, TX 77802.	450011	06/14/2006	TX.	
Steinberg Diagnostic (SDMI), 2850 Siena Heights, Henderson, NV 89052.	WCHCC	06/14/2006	NV.	
Raritan Bay Medical Center, 1 Hospital Plaza, Old Bridge, NJ 08857.	310039	06/14/2006	NJ.	
MRI Center—St. Anne Mercy Hospital, 3404 W. Sylvania Avenue, Toledo, OH 43623.	360262	06/14/2006	OH.	
MRI Center—St. Charles Mercy Hospital, 2600 Navarre Avenue, Oregon, OH 43616.	360081	06/14/2006	OH.	
MRI Center—St. Luke's Hospital, 2901 Monclova Road, Maumee, OH 43537.	360090	06/14/2006	OH.	
MRI Center—St. Vincent Medical Center, 2213 Cherry Street, Toledo, OH 43608.	360112	06/14/2006	OH.	
MRI Center—Toledo Hospital, 2142 N. Cove Boulevard, Toledo, OH 43606.	360068	06/14/2006	OH.	
McAlester Regional Health Center, One Clark Bass Boulevard, McAlester, OK 74501.	370034	06/14/2006	OK.	
Express Imaging Center, Ltd., 1987 West Fourth Street, Mansfield, OH 44906.	9299151	06/14/2006	OH	Suite A.
Mercy Regional Medical Center, 375 East Park Avenue, Durango, CO 81301.	60013	06/14/2006	CO.	
Texas Oncology—Longview Cancer Center PET, 1300 N. Fourth Street, Longviews, TX 75601.	00T35E	06/14/2006	TX.	
UNC Hospitals, 101 Manning Drive, Chapel Hill, NC 27514	3400610	06/14/2006	NC	PET Department. Basement W/C Hospital.
DeKalb Medical Center—Diagnostic Imaging Center, 2701 North Decatur Road, Decatur, GA 30033.	110076	06/14/2006	GA.	
Long Island Pet Imaging, 6 Ohio Drive, Lake Success, NY 11042.	W4921	06/14/2006	NY	Suite 101.
Vanderbilt University Medical Center, 1161 21st Avenue South, Nashville, TN 37232.	3284867	06/14/2006	TN	Building 1251 RRB.
Medical Outsourcing Services, LLC, 1800 E. Lakeshore DriveDecatur, IL 62521.	211224	06/14/2006	IL.	
New York PET and CTA Imaging Center, 7404 5th Avenue, Brooklyn, NY 11209.	1083680003	06/14/2006	NY.	
Mercy Medical Center—North Iowa, 1000 4th Street SW, Mason City, IA 50401.	160064	06/14/2006	IA.	
Lawrence and Memorial Hospital, 365 Motauk Avenue, New London, CT 06320.	70007	06/14/2006	CT.	
Superior Medical Diagnostics II, LLC, 235 Franklin Avenue, Nutley, NJ 07110.	68423	06/14/2006	NJ.	
Oncology Specialists, S.C., 7900 N. Milwaukee Avenue, Niles, IL 60714.	587940	06/14/2006	IL	Suite 16.
Hahnemann University Hospital, Broad & Vine, MS300, Philadelphia, PA 19102.	390290	06/14/2006	PA.	
Shrewsbury Diagnostic Imaging, LLC, 1131 Broad Street, Shrewsbury, NJ 07702.	24021	06/14/2006	NJ	Suite 110.
Medical Outsourcing Services, LLC, 500 West Court Street, Kankakee, IL 60901.	211224	06/14/2006	IL.	
Forsyth Medical Center, 3333 Silas Creek Parkway, Winston Salem, NC 27103.	3400014	06/14/2006	NC.	
Medical Outsourcing Services, LLC, 500 John Deere Road, Moline, IL 61265.	211224	06/14/2006	IL.	

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Medical Outsourcing Services, LLC, 836 W. Wellington Avenue, Chicago, IL 60657.	211222	06/14/2006	IL.	
Medical Outsourcing Services, LLC, 1600 West Walnut, Jacksonville, IL 62650.	211224	06/14/2006	IL.	
Medical Outsourcing Services, LLC, 1600 23rd Street, Bedford, IN 47471.	223260	06/14/2006	IN.	
Medical Outsourcing Services, LLC, 1500 North Ritter Avenue, Indianapolis, IN 46219.	223260	06/14/2006	IN.	
Medical Outsourcing Services, LLC, 1221 N. Highland, Aurora, IL 60506.	211223	06/14/2006	IL.	
Medical Outsourcing Services, LLC, 1000 Lincoln Health Center Drive, Mattoon, IL 61938.	211224	06/14/2006	IL.	
Salinas Valley Memorial Healthcare System, 450 E. Romie Lane, Salinas, CA 93901.	50334	06/14/2006	CA.	
Bridgeport Hospital, 267 Grant Street, Bridgeport, CT 06610	70010	06/14/2006	CT.	
MRIGP, Inc., d.b.a. Advanced Medical Imaging Diamond H., 2490 W 26th Avenue, Suite 20A, Denver, CO 80211.	H8808	06/14/2006	CO.	
RCHO PET Imaging, 5120 Belfort Boulevard, Suite 130, Jacksonville, FL 32256.	40259	06/14/2006	FL.	
Presbyterian Hospital, 200 Hawthorne Lane, Charlotte, NC 28204.	560554230	06/14/2006	NC.	
Eisenhower Imaging Center, 39000 Bob Hope Drive, Rancho Mirage, CA 92210.	ZZZ91572Z	06/14/2006	CA	Lower Level Lucy Curci Cancer Center.
Mississippi Baptist Medical Center, 501 Marshall Street, Jackson, MS 39202.	250102	06/14/2006	MS.	
Texas Oncology—South Texas Cancer Center, 2121 Pease Street, Suite 101, Harlingen, TX 78550.	14041756	06/14/2006	TX	Texas Oncology—South Texas Cancer Center.
Valley Radiologists, Ltd.—Paseo II Office, 5605 W. Eugie Avenue, Suite 110, Glendale, AZ 85304.	WCFHS	06/14/2006	AZ.	
Good Samaritan Hospital, 400 15th Avenue SE, Puyallup, WA 98372.	500079	06/14/2006	WA.	
St. John's Mercy Hospital, 851 5th Street, Washington, MO 63090.	260052	06/14/2006	MO.	
Memorial Hermann The Woodlands OPID, 9200 Pinecroft Drive, Suite 100, The Woodlands, TX 77380.	741152597	07/14/2006	TX.	
St. Luke's Hospital, 232 South Wood's Mill Road, Chesterfield, MO 63017.	260179	07/14/2006	MO.	
Lake Vista Cancer Center, 2790 Lake Vista Drive, Lewisville, TX 75067.	00543K	07/14/2006	TX.	
Palms Imaging Medical Group, Inc., 1901 Outlet Center Drive, Oxnard, CA 93036.	W19564	07/14/2006	CA.	
Houston Medical Imaging, LLC, 3310 Richmond Avenue, Houston, TX 77006.	00137K	07/14/2006	TX.	
Alliance Imaging—West Anaheim Medical Center, 3033 W. Orange Avenue, Anaheim, CA 92804.	TD017	07/14/2006	CA.	
Winthrop PET Imaging Center, 222 Station Plaza North, Suite 140, Mineola, NY 11501.	330167	07/14/2006	NY.	
Greenville Hospital System, University Medical Center, 701 Grove Road, Greenville, SC 29605.	420078	07/14/2006	SC.	
High Field Open MRI, 1895 Jefferson Road, Rices Landing, PA 15357.	7885	07/14/2006	PA.	
PET/CT Center at St. Anthony's POB, 1201 5th Avenue North, St. Petersburg, FL 33705.	E5753	07/14/2006	FL	Suite 100.
Texas Oncology—Deke Slayton Cancer Center, 501 Medical Center, Webster, TX 77598.	00t40e	07/14/2006	TX.	
Invision North Florida Outpatient Imaging Center, 6605 NW 9th Boulevard, Gainesville, FL 32609.	E4639	07/14/2006	FL.	
Memorial Hospital of Union County, 500 London Avenue, Marysville, OH 43040.	360092	07/14/2006	OH.	
Texas Oncology/South Texas Cancer Center—McAllen, 1901 S. 2nd Street, McAllen, TX 78503.	00N39J	07/14/2006	TX.	
Baylor Medical Center at Irving, 1901 North MacArthur Boulevard, Irving, TX 75061.	450079	07/14/2006	TX.	
Providence Park Hospital, 47601 Grand River Avenue, Novi, MI 48374.	230019	07/14/2006	MI.	
Texas Oncology—Abilene, 1957 Antilley Road, Abilene, TX 79606.	140414748	07/14/2006	TX.	
St. Anthony Hospital, 1000 North Lee Street, Oklahoma City, OK 73101.	370037	07/14/2006	OK.	
Rice Memorial Hospital, 301 Becker Avenue SW, Willmar, MN 56201.	240088	07/14/2006	MN.	
LDS Hospital Nuclear Medicine, 8th Avenue & C Street, Salt Lake City, UT 84143.	460010	07/14/2006	UT.	

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RMG First & Laurel Imaging Center, 2466 First Avenue, San Diego, CA 92101.	W14057	07/14/2006	CA.	
RMG Gardenview Imaging Center, 1200 Gardenview Road, Encinitas, CA 92024.	W14057F	07/14/2006	CA	Suite 110.
Decatur County Memorial Hospital, 720 North Lincoln Street, Greensburg, IN 47240.	150062	07/14/2006	IN.	
Midland Imaging Center, 5001 Andrews Highway, Midland, TX 79703.	00U75H	07/14/2006	TX.	
Advanced Imaging, LLC, 3433 NW 56th C–10, Oklahoma City, OK 73112.	400522379	07/14/2006	OK.	
University of Iowa Hospitals and Clinics, 200 Hawkins Drive, Iowa City, IA 52242.	160058	07/14/2006	IA.	
AZ Oncology Associates PET/CT & CT Imaging Center, 2070 W. Rudasill Road, Tucson, AZ 85704.	25291	07/14/2006	AZ	Suite 110.
Medical Diagnostic Imaging, 14 Raymond Avenue, Poughkeepsie, NY 12603.	EEN841	07/14/2006	NY.	
Shore Memorial Hospital, 10085 William F. Bernart Circle, Nassawadox, VA 23413.	540560500	07/14/2006	VA.	
Deaconess Hospital, 600 Mary Street, Evansville, IN 47747	150082	07/14/2006	IN.	
Great Neck Imaging, PC, 907 Northern Boulevard, Great Neck, NY 11021.	1487646311	07/14/2006	NY.	
FMH Rose Hill, 1562 Opossumtown Pike, Frederick, MD 21702	KP72	07/14/2006	MD.	
Oakwood Annapolis Hospital, 33155 Annapolis Road, Wayne, MI 48184.	230142	07/14/2006	MI.	
The Regional Cancer Center, 2500 West 12th Street, Erie, PA 16505.	140052	07/14/2006	PA.	
Meritcare Hospital, 801 North Broadway, Fargo, ND 58122	350011	07/14/2006	ND.	
Community Hospitals and Wellness Centers, 433 W. High Street, Bryan, OH 43506.	360121	07/14/2006	OH.	
Sacred Heart Hospital, 900 W. Clairemont Avenue, Eau Claire, WI 54701.	520013	07/14/2006	WI.	
Via Radiology—Meridian Pavilion, 11011 Meridian Avenue North #101, Seattle, WA 98133.	8859612	07/14/2006	WA.	
Medical Outsourcing Services, LLC, 2200 Market Street, Charlestown, IN 47111.	223260	07/14/2006	IN.	
Allegheny General Hospital, 320 East North Avenue, Pittsburgh, PA 15232.	60503	07/14/2006	PA	Division of Nuclear Medicine.
Texas Oncology—12th Avenue, 1001 W. 12th Avenue, Fort Worth, TX 76104.	00R66C	07/14/2006	TX.	
Southwest Fort Worth Cancer Center, 6500 Harris Parkway, Fort Worth, TX 76132.	00R66C	07/14/2006	TX.	
St. Rita's Medical Center, 730 W. Market Street, Lima, OH 45801.	360066	07/14/2006	OH.	
New Mexico Oncology Hematology Consultants, Ltd., 4901 Lang Avenue NE, Albuquerque, NM 87109.	850367056	07/14/2006	NM.	
Emory Eastside Medical Center, 545 Old Norcross Road, Lawrenceville, GA 30045.	110192	07/14/2006	GA	Suite 200.
Riverside Regional Medical Center, 500 J. Clyde Morris Boulevard, Newport News, VA 23601.	490052	07/14/2006	VA.	
Connecticut Oncology & Hematology, 220 Kennedy Drive, Torrington, CT 06790.	C00633	07/14/2006	CT.	
Chilton Memorial Hospital, 97 West Parkway, Pompton Plains, NJ 07444.	310017	07/14/2006	NJ.	
Riverside Diagnostic Center Williamsburg, 120 Kings Way, Williamsburg, VA 23188.	490052	07/14/2006	VA.	
Lawrence County MRI & Diagnostic Imaging Center, 2526 Wilmington Road, New Castle, PA 16105.	68617	07/14/2006	PA.	
Joint Township District Memorial Hospital, 200 St. Clair Street, Saint Marys, OH 45885.	360032	07/14/2005	OH.	
Radiation Therapy Regional Centers, 3680 Broadway, Fort Myers, FL 33901.	77215	07/14/2006	FL.	
Graduate Hospital, 1800 Lombard Street, Philadelphia, PA 19146.	390285	07/14/2006	PA	One Graduate Hospital.
Columbia Diagnostic Center, 1111 Paulison Avenue, Clifton, NJ 07015.	94729	07/14/2006	NJ.	
The Nebraska Medical Center, 4250 Dewey Avenue, Omaha, NE 68113.	280013	07/14/2006	NE.	
Memorial Hermann Memorial City OPID, 925 Gessner Road, Houston, TX 77024.	741152597	07/14/2006	TX.	
Clifton Springs Hospital and Clinic, 2 Coulter Road, Clifton Springs, NY 14432.	330265	07/14/2006	NY.	
Monongalia General Hospital, 1200 J. D. Anderson Drive, Morgantown, WV 26505.	510024	07/14/2006	WV	Monongalia General Hospital.

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Providence Portland Medical Center, 4805 NE Glisan Street, Portland, OR 97213.	380061	07/14/2006	OR.	
Highfield Open MRI, Inc., 995 GreenTree Road, Pittsburgh, PA 15220.	7885	07/14/2006	PA.	
Providence St. Vincent Medical Center, 9205 SW Barnes Road, Portland, OR 97225.	380004	07/14/2006	OR.	
Conway Regional Imaging Center, 2120 Robinson Avenue, Conway, AR 72034.	40029	07/14/2006	AR.	
Martin Memorial Medical Center, 300 Hospital Avenue, Stuart, FL 34994.	100044	07/14/2006	FL.	
Northwest Medical Foundation of Tillamook, 1000 Third Street, Tillamook, OR 97141.	381317	07/14/2006	OR	Tillamook County General Hospital.
O'Connor Hospital, 2105 Forest Avenue, San Jose, CA 95128–1471.	50153	07/14/2006	CA.	
Midtown Imaging, LLC—Wellington, 440 N. State Road 7, Wellington, FL 33411.	E9133	07/14/2006	FL.	
Midtown Imaging, LLC—Jupiter, 345 Jupiter Lakes Boulevard, Jupiter, FL 33458.	E9133	07/14/2006	FL	Suite 100.
MMI/Mid Coast Hospital, 51 US Route 1, Scarborough, ME 04074.	327079	07/14/2006	ME	Suite O.
Molecular Imaging Institute, 5349 Commerce Boulevard, Crown Point, IN 46307.	192870	07/14/2006	IN.	
RCOA Imaging Services, 11937 US Highway 271, Tyler, TX 75708.	FTN022	07/14/2006	TX.	
MMI/Maine Medical Center, 51 US Route 1, Scarborough, ME 4074.	327079	07/14/2006	ME	Suite O.
Radiology, Ltd., 4640 East Camp Lowell Drive, Tucson, AZ 85712.	WCBBM	07/14/2006	AZ.	
Intermed Oncology Associates, S.C., 6701 159th Street, Tinley Park, IL 60477.	610860	07/14/2006	IL.	
Lakes Radiology, 450 Canisteo Street, Hornell, NY 14843	1710937727	07/14/2006	NY.	
Opelousas PET/CT Imaging Center, 3975 I–49 South Service Road, Suite 100, Opelousas, LA 70570.	5DA11	07/14/2006	LA.	
Florida Cancer Institute—BRK, 7154 Medical Center Drive, Spring Hill, FL 34608.	1427017326	08/07/2006	FL.	
Capital Health System, 446 Belleview Avenue, Trenton, NJ 08618.	310044	08/07/2006	NJ.	
Hudson Valley Diagnostic Imaging, PLLC, 575 Hudson Valley Avenue, New Windsor, NY 12553.	WBH241	08/07/2006	NY.	
St Joseph's Hospital, 3200 Pleasant Valley Road, West Bend, WI 53095.	520063	08/07/2006	WI.	
Atlantic Medical Imaging, 30 East Maryland Avenue, Somers Point, NJ 08244.	101024	08/07/2006	NJ.	
Providence Imaging Center, 3340 Providence Drive, Anchorage, AK 99508.	2085R0202X	08/07/2006	AK.	
Rochester Radiology Associates, PC, 1277 Portland Avenue, Rochester, NY 14621.	199726	08/07/2006	NY.	
Melbourne Internal Medicine Associates, 1132 South Hickory Street, Melbourne, FL 32901.	77167	08/07/2006	FL.	
Highline Imaging, LLC, 275 SW 160th Street, Seattle, WA 98166.	8801784	08/07/2006	WA.	
Tyler PET, 415 South Fleishel Avenue, Tyler, TX 75702	752131429	08/07/2006	TX.	
Lake City Medical Center, 340 NW Commerce Drive, Lake City, FL 32055.	100156	08/07/2006	FL.	
Blount Memorial Hospital, 907 East Lamar Alexander Boulevard, Maryville, TN 37804.	440011	08/07/2006	TN.	
Texas Cancer Center Mesquite, 4700 North Galloway, Mesquite, TX 75150.	R339	08/07/2006	TX.	
Rutland Regional Medical Center: Diagnostic Imaging, 160 Allen Street, Rutland, VT 05701.	470005	08/07/2006	VT.	
MDMED, Inc., 155 Calle Portal, Suite 700, Sierra Vista, AZ 85635.	Z68496	08/07/2006	AZ.	
Atlantic Medical Imaging Wall Township, 2399 North Highway 34, Manasquan, NJ 08736.	101024	08/07/2006	NJ	Ramshorn Executive Centre Bldg B.
Newport Imaging Center, 455 Old Newport Road, Suite 101, Newport Beach, CA 92660.	W10829	08/07/2006	CA.	
Cancer Care and Hematology Specialists (CCHSC), 8915 West Golf Road, Niles, IL 60714–05825.	355030	08/07/2006	IL.	
Hematology Oncology Associates of Illinois (HOAI), 715 West North Avenue, Melrose Park, IL 60160.	218860	08/07/2006	IL.	
Princeton Community Hospital, 122 12th Street Ext, Princeton, WV 24740.	510046	08/07/2006	WV	PO Box 1369.
TRICAT, LLC at Edison, 3830 Park Avenue, Edison, NJ 08820	27193	08/07/2006	NJ	Suite 102.

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Olathe Medical Center, 20333 W. 151st Street, Olathe, KS 66061.	170049	08/07/2006	KS.	
St. Joseph Hospital, 1140 West La Veta Avenue, Orange, CA 92868.	50069	08/07/2006	CA	2nd Floor Nuclear Medicine.
Baptist Health Medical Center, 9601 I630, Exit 7, Little Rock, AR 72205–7299.	40114	08/07/2006	AR.	
Florida Cancer Specialists, 3840 Broadway, Fort Myers, FL 33901.	1225064520	08/07/2006	FL.	
Pacca PET Imaging, 5210 Belfort Road, Suite 130, Jacksonville, FL 32256.	37572	08/07/2006	FL.	
National PET Scan Palm Beach, LLC, 16110 Jog Road, Delray Beach, FL 33484.	1164452405	08/07/2006	FL	Suite 200.
Central Memphis Regional PET Imaging Center, LLC, 1388 Madison Avenue, Memphis, TN 38104.	1295719110	08/07/2006	TN.	
Johnston Memorial Hospital, 351 Court Street NE, Abingdon, VA 24210.	490053	08/07/2006	VA.	
Lenox Hill Hospital, 100 East 77th Street, New York, NY 10021	131624070	08/07/2006	NY.	
Mercy Medical Center, 411 Laurel Street, Suite 2310, Des Moines, IA 50314.	160083	08/07/2006	IA.	
New Orleans Regional PET Center, LLC, 3434 Prytania Street, Suite 120, New Orleans, LA 70115.	1538143474	08/07/2006	LA.	
Indiana Regional Medical Center PET Imaging, 835 Hospital Road, Indiana, PA 15701.	390173	08/07/2006	PA	PO Box 788.
Mid American—Defiance Clinic, 1400 E. Second Street, Defiance, OH 43512.	ID00809	08/07/2006	OH.	
Total Imaging Robertson, 737 West Brandon Boulevard, Brandon, FL 33511.	k7282	08/07/2006	FL.	
New Tampa Imaging Center, 14302 N. Bruce B. Downs Boulevard, Tampa, FL 33613.	k57209	08/07/2006	FL.	
Summit Imaging, 12037 Cortez Boulevard, Brooksville, FL 34613.	40986	08/08/2006	FL.	
University of NM Cancer Research & Treatment Center, 900 Caminodey Salud NE, Albuquerque, NM 87131.	400521103	08/08/2006	NM.	
Alliance Imaging—Los Alamitos Med Center, 3751 Katella Avenue, Los Alamitos, CA 90720.	TD017	08/08/2006	CA.	
NYU Clinical Cancer Center, Diagnostic Imaging, 160 E. 34th Street, New York, NY 10016.	W1L361	08/08/2006	NY	2nd Floor.
Margaret Mary Community Hospital, 321 Mitchell Avenue, Batesville, IN 47006.	151329	08/08/2006	IN.	
Quantum PET—Apple Hill, 37 Monument Road, York, PA 17403.	40635	08/08/2006	PA.	
Memorial Hospital, 1204 N. Mound Street, Nacogdoches, TX 75961.	450508	08/08/2006	TX.	
BMH—DeSoto, 7601 Southcrest Parkway, Southaven, MS 38671.	250141	08/08/2006	MS.	
Riverside Medical Center, 300 Bourbonnais Campus, Bourbonnais, IL 60914.	140186	08/08/2006	IL	Riverside Medical Center.
UCSD Center for Molecular Imaging, 11388 Sorrento Valley Road, Suite 100, San Diego, CA 92121.	TG302	08/08/2006	CA.	
Imaging Partners at Valley, LLC, 400 South 43rd Street, Renton, WA 98055.	AB38657	08/08/2006	WA	Olympic Building.
El Paso Cancer Treatment Center, 7848 Gateway East Boulevard, El Paso, TX 79915.	00543K	08/08/2006	TX.	
Desert Radiologists, 3930 S. Eastern Avenue, Las Vegas, NV 89119.	VWCCBT	08/08/2006	NV.	
Saint Joseph Hospital, 2900 North Lake Shore Drive, Chicago, IL 60068.	140224	08/08/2006	IL.	
Midstate Medical Center, 435 Lewis Avenue, Meriden, CT 06451.	60646715	08/08/2006	CT.	
Brookville Hospital, 100 Hospital Road, Brookville, PA 15825	391312	08/08/2006	PA.	
Suntree Diagnostic Center, 6300 N. Wickham Road, Suite 101, Melbourne, FL 32940.	701	08/08/2006	FL.	
Virginia Mason Medical Center, 1100 Ninth Avenue, Seattle, WA 98101.	500005	08/08/2006	WA.	
Van Wert County Hospital, 1250 South Washington Street, Van Wert, OH 45891.	360071	08/08/2006	OH.	
Manhasset Diagnostic Imaging, PC, 1350 Northern Boulevard, 2nd Floor, Manhasset, NY 11030.	W14841	08/08/2006	NY.	
Southern New Mexico Cancer Center, 150 Road Runner Parkway, Las Cruces, NM 88011.	752131429	08/08/2006	NM.	
Davis Memorial Hospital, Gorman Avenue and Reed Street, Elkins, WV 26241.	510030	08/08/2006	WV	Gorman Avenue.
Advocate Good Samaritan Hospital, 3815 Highland Avenue, Downers Grove, IL 60515.	140288	08/08/2006	IL.	

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Benefis Healthcare, 1101 26th Street South, Great Falls, MT 59405.	270012	08/08/2006	MT.	
Fort Walton Beach Medical Center, 1032 Mar Walt Drive, Fort Walton Beach, FL 32547.	100223	08/08/2006	FL.	
Blessing Hospital, PO Box #7005, Quincy, IL 62305	140015	08/08/2006	IL.	
Alliance Imaging—Allen County Hospital, 101 South 1st Street, Iola, KS 53808.	130656	08/08/2006	KS.	
Florida Cancer Institute—NPR, 8763 River Crossing Boulevard, New Port Richey, FL 34655.	1427017326	08/08/2006	FL.	
Kimball Medical Center, 600 River Avenue, Lakewood, NJ 08701.	315084	08/08/2006	NJ.	
Radiology Imaging Associates at Heritage, 8926 Woodyard Road, Clinton, MD 20735.	521454775	08/08/2006	MD	Suite 502.
Immanuel Medical Center, 6901 North 72nd Street, Omaha, NE 68122.	280081	08/08/2006	NE.	
North Fork Radiology, 1333 Roanoke Avenue, Riverhead, NY 11901.	w11401	08/08/2006	NY.	
South County PET Imaging, LLC, 10010 Kennerly Road, St. Louis, MO 63128.	93053	08/08/2006	MO.	
Carolinas Hospital System, 805 Pamplico Highway, Florence, SC 29505.	621587267	08/08/2006	SC.	
Radiology Associates of San Luis Obispo, 522 E. Plaza Drive, Santa Maria, CA 93454.	GR0009774	08/08/2006	CA.	
Florida Cancer Specialists—Port Charlotte, 22395 Edgewater Drive, Port Charlotte, FL 33980.	1225064520	08/08/2006	FL.	
Florida Cancer Specialists—Venice, 901 South Tamiami Trail, Venice, FL 34285.	1225064520	08/08/2006	FL.	
Florida Cancer Specialists—Bradenton, 6001 21st Avenue West, Bradenton, FL 34209.	1225064520	08/08/2006	FL.	
Nebraska Methodist Hospital, 8303 Dodge Street, Omaha, NE 68114.	280040	08/08/2006	NE.	
PET/CT Center of Richardson, 399 Melrose Drive, Richardson, TX 75080.	1740207539	08/08/2006	TX	Suite A.
Molecular Imaging at Sequoia Imaging Center, 4949 W. Cypress Avenue, Visalia, CA 93277.	ZZZ27463Z	08/08/2006	CA.	
Central Jersey Radiologists, 2128 Kings Highway, Oakhurst, NJ 07755.	527995	08/08/2006	NJ.	
Claxton-Hepburn Medical Center, 214 King Street, Ogdensburg, NY 13669.	330211	08/08/2006	NY.	
Memorial Hermann Southeast, 11800 Astoria Boulevard, Houston, TX 77089.	741152597	08/08/2006	TX.	
NSMS—Pine Bluff, AR, 4253 Argosy Court, Madison, WI 53714	5f168	08/08/2006	WI.	
Yuma Regional Medical Center, 2400 S. Avenue A, Yuma, AZ 85364.	866007596	08/08/2006	AZ.	
Carle Clinic, 1702 S. Mattis Avenue, Champagne, IL 61820	371188284	08/08/2006	IL.	
North Shore—LIJ Center for Advanced Medicine, 450 Lakeville Road, Lake Success, NY 11042.	330106	08/08/2006	NY	North Shore—LIJ Center for Advanced Medicine Diagnostic Imaging Center.
McAlester Diagnostic Imaging, 10 South Third Street, McAlester, OK 74501.	1760411540	08/08/2006	OK	Suite 100.
California Imaging Institute, 1867 E. Fir Avenue, Fresno, CA 93720.	ZZZ03565Z	08/08/2006	CA.	
Bon Secours Memorial Regional Medical Center, 8260 Atlee Road, Mechanicsville, VA 23116.	541744931	08/08/2006	VA.	
University of Maryland Medical Center, 22 S. Greene Street Gudelksy 2nd Floor, Baltimore, MD 21201.	210002	08/08/2006	MD	Division of Nuclear Medicine.
Bixby Medical Center, 818 Riverside Avenue, Adrian, MI 49221	230005	08/08/2006	MI.	
Kern Radiology Medical Group, 2301 Bahamas Drive, Bakersfield, CA 93309.	1720023997	08/08/2006	CA.	
Bon Secours St. Francis Medical Center, 13710 St. Francis Boulevard, Midlothian, VA 23114.	311716973	08/08/2006	VA.	
MMI/Maine General Waterville, 51 US Route 1, Scarborough, ME 04074.	327079	08/08/2006	ME	Suite O.
Mount Adams Imaging Center, 3911 Castlevale Road, Yakimaw, WA 98902.	8857843	08/08/2006	WA.	
Carilion Roanoke Memorial Hospital, 2001 Crystal Spring Avenue, Roanoke, VA 24014.	490024	08/08/2006	VA.	
Seton Medical Center; Nuclear Medicine Dept., 1900 Sullivan Avenue, Daly City, CA 94015–2229.	50289	08/08/2006	CA.	
Arnett Imaging Center, 2403 Loy Drive, Lafayette, IN 47909	224390	08/08/2006	IN.	
Advanced Diagnostic Imaging, PC, 1120 Professional Boulevard, Evansville, IN 47630.	639970	08/08/2006	IN.	

Facility name	Provider number	Date approved	State	Other information
Queen of Peace Hospital, 301 Second Street NE, New Prague, MN 56071.	241361	08/08/2006	MN.	
Agnesian Health Care, 430 E. Division Street, Fond du Lac, WI 54935.	520088	08/08/2006	WI.	
ACMH Hospital, One Nolte Drive, Kittanning, PA 16201	390163	08/08/2006	PA.	
Wilshire Oncology Medical Group, Inc., 1280 Corona Pointe Court, Corona, CA 92879.	zzz19568z	08/08/2006	CA	Suite 112.
United Radiology—Laurel, 14201 Laurel Park Drive, Laurel, MD 20707.	2.01558E+11	08/08/2006	MD	Suite 208.
Bay Area Medical Center, 3100 Shore Drive, Marinette, WI 54143.	520113	08/08/2006	WI.	
Penn State Milton S. Hershey Medical Center, 500 University Drive, Hershey, PA 17033.	251854772	08/08/2006	PA	HG380.
Delta St. Joseph's MRI, LLC, 1617 N. California Street, Stockton, CA 95204.	ZZZ19725Z	08/08/2006	CA	Suites 1A and 1B.
United Radiology: Bowie, 16701 Melford Boulevard, Bowie, MD 20715.	2.01558E+11	08/08/2006	MD.	
United Radiology Gaithersburg, 702 Russell Avenue, Gaithersburg, MD 20877.	2.01558E+11	08/08/2006	MD.	
United Radiology Olney, 18120 Hillcrest Drive, Olney, MD 20832.	2.01558E+11	08/08/2006	MD	Suite A.
FCS/Axcess Diagnosis/Sarasota, 600 N. Cattleman Road, Sarasota, FL 34232.	1225064520	08/08/2006	FL.	
NSMS—Greenville, IL, 4253 Argosy Court, Madison, WI 53714	208196	08/08/2006	WI.	
FCS/Axcess Diagnosis/Venice, 842 Sunset Lake Boulevard, Venice, FL 34292.	1225064520	08/08/2006	FL	Suite #301.
Leading Edge Radiation, 8715 5th Avenue, Brooklyn, NY 11209	WEM111	09/05/2006	NY.	
Rena Tarbet Cancer Center, 4201 Medical Center Drive, Suite 180, McKinney, TX 75069.	oow753	09/05/2006	TX.	
McLaughlin & Marte, M.D, LLP, 3850 Tampa Road, Suite 202, Palm Harbor, FL 34684.	1003862079	09/05/2006	FL.	
BryanLGH Medical Center, 2300 South 16th Street, Lincoln, NE 68502.	280003	09/05/2006	NE.	
Freehold MR Associates, 691 West Main Street, Freehold, NJ 07728.	405856	09/05/2006	NJ.	
Franciscan Skemp Healthcare, 700 West Avenue South, La Crosse, WI 54601.	520004	09/05/2006	WI.	
Teton Radiology, 2001 S. Woodruff, Suite 17, Idaho Falls, ID 83404.	1371462	09/05/2006	ID.	
Fletcher Allen Health Care, Mobile Pad, 790 College Parkway, Colchester, VT 05446.	1659309615	09/05/2006	VT	790 College Parkway.
University of Penn Imaging Center, 3600 Market Street, 3rd Floor Silverstein, Philadelphia, PA 19104.	764089	09/05/2006	PA.	
Sitron-Hammel Radiology Group, 4277 Hempstead Turnpike, Suite 200, Bethpage, NY 11714.	W14891	09/05/2006	NY.	
MRI of Saint Louis Obispo, 1064 Murray Avenue, San Luis Obispo, CA 93405.	1881661361	09/05/2006	CA.	
Lahey Clinic, 41 Mall Road, Burlington, MA 01805	220171	09/05/2006	MA.	
St. Joseph Medical Center, 215 N. 12th Street, Reading, PA 19603.	390096	09/05/2006	PA.	
Spartanburg Regional Medical Center, 101 E. Wood Street, Spartanburg, SC 29303.	420007	09/05/2006	SC.	
Aurora Sinai Medical Center, 945 N. 12th Street, Milwaukee, WI 53201.	520064	09/05/2006	WI.	
FHN Memorial Hospital, 1045 W. Stephenson Street, Freeport, IL 61032.	140160	09/05/2006	IL.	
Southwest Washington Medical Center, 400 NE Mother Joseph Place, Vancouver, WA 98668.	500050	09/05/2006	WA.	
St. Lukes Center for Diagnostic Imaging, 6 McBride and Sons Corporate Center Drive, Suite 101, Chesterfield, MO 63005.	47006	09/05/2006	MO.	
The Stamford Health System, Shelbourn Road & West Broad Street, Stamford, CT 06904.	70006	09/05/2006	CT.	
Hagerstown Imaging, LLC, 1150 A Professional Court, Hagerstown, MD 21741.	1518914936	09/05/2006	MD.	
GCM Suburban Imaging, 6420 Rockledge Drive, Suite 3100, Bethesda, MD 20817.	409623	09/05/2006	MD.	
Alliance Imaging—No. Idaho Imaging, 2003 Lincoln Way, Coeur d'Alene, ID 83814.	1790291	09/05/2006	ID.	
HPMA PET Center, 22710 Professional Drive, Suite 104, Kingwood, TX 77339.	0019BY	09/05/2006	TX.	
Parma Community General Hospital, 7007 Powers Boulevard, Parma, OH 44129.	360041	09/05/2006	OH.	
Pacific Shores Medical Group PET Imaging, 1043 Elm Street #104, Long Beach, CA 90813.	W13494	09/05/2006	CA.	

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Clark Memorial Hospital, 1220 Missouri Avenue, Jeffersonville, IN 47130.	15009	09/05/2006	IN.	
Abilene Imaging Center, LLC, 750 North 18th Street, Abilene, TX 79601.	FTA070	09/05/2006	TX.	
DuBois Regional Medical Center, 100 Hospital Avenue, DuBois, PA 15801.	390086	09/06/2006	PA.	
Meeker County Memorial Hospital, 612 South Sibley Avenue, Litchfield, MN 55355.	241366	09/06/2006	MN.	
Memorial Health, 4700 Waters Avenue, Savannah, GA 31403 ..	110036	09/06/2006	GA.	
St. Luke's Regional Medical Center, Ltd., 190 E. Bannock Street, Boise, ID 83712.	130006	09/06/2006	ID.	
Radiology Consultants Imaging Center, 400 Avenue K, SE, Winter Haven, FL 33880.	U3944	09/06/2006	FL.	
Patient Comprehensive Cancer Center, 4352 North Josey Lane, Carrollton, TX 75010.	0083BY	09/06/2006	TX.	
The University of Tennessee Medical Center, 1924 Alcoa Highway, Knoxville, TN 37920.	440015	09/06/2006	TN.	
Radiation Therapy Regional Centers—Naples, 800 Goodlette Road, Suite 110, Naples, FL 34102.	77215	09/06/2006	FL.	
St. Mary's Medical Center, 2900 First Avenue, Huntington, WV 25702.	510007	09/06/2006	WV.	
McKinney Regional Cancer Center, 4601 Medical Center Drive, McKinney, TX 75069.	00711W	09/06/2006	TX.	
WCA Hospital, PO Box 840, Jamestown, NY 14701	330239	09/06/2006	NY	207 Foote Avenue.
Grants Pass Imaging and Diagnostic Center, LLC, 1619 NW Hawthorne, Suite 110, Grants Pass, OR 97526.	1659307973	09/06/2006	OR.	
Baptist Memorial Hospital—Golden Triangle, 2520 5th Street North, Columbus, MS 39705.	250100	09/06/2006	MS.	
Florida Medical Clinic, 13417 US Highway 301, Dade City, FL 33525.	39715	09/06/2006	FL.	
Saint Clare's Hospital, 400 West Blackwell Street, Dover, NJ 07801.	310067	09/06/2006	NJ.	
Radiation Medicine Associates, 2202 South 77 Sun Shine Strip, Suite E, Harlingen, TX 78550.	00645N	09/06/2006	TX.	
The Radiology Clinic, LLC, 208 McFarland Circle North, Tuscaloosa, AL 35406.	13089	09/06/2006	AL.	
Bay Area Hospital, 1775 Thompson Road, Coos Bay, OR 97420.	30090	09/06/2006	OR.	
MMI/St. Mary's Hospital, 51 US Route 1, Scarborough, ME 04074.	327079	09/06/2006	ME	Suite O.
Gulf Coast Medical Diagnostic Center, 2024 State Avenue, Panama City, FL 32405.	30930	09/06/2006	FL.	
Diagnostic Radiology Systems, Inc., 1010 Medical Center Drive, Powderly, KY 42366.	9366001	09/06/2006	KY.	
Lewis Gale Medical Center, 1900 Electric Road, Salem, VA 24153.	490048	09/06/2006	VA.	
Radiology Diagnostic Center, 1310 Las Tablas Road, Suite 103, Templeton, CA 93465.	W7491	09/06/2006	CA.	
Weslaco Nuclear Imaging Center, 913 S. Airport Drive, Weslaco, TX 78596.	1780796219	09/06/2006	TX.	
Pioneer PET, LLC, 1930 E. Southern Avenue, Tempe, AZ 85282.	1265401996	12/05/2006	AZ.	
Kearney Imaging Center, LLC, 3219 Central Avenue, Suite 109, Kearney, NE 68847.	98950	12/05/2006	NE.	
Rose Medical Center, 4567 East 9th Avenue, Denver, CO 80220.	841321373	12/05/2006	CO.	
UCSF Medical Center, 185 Berry Street, San Francisco, CA 94107.	50454	12/05/2006	CA	Lobby 7, Suite 180.
Broward General Medical Center, 1500 S. Andrews Avenue, Fort Lauderdale, FL 33316.	100039	12/05/2006	FL.	
St. Paul Radiology, PA/Midwest Radiology, 166 Fourth Street East, St. Paul, MN 55101.	CO2661	12/05/2006	MN.	
Queen of the Valley Hospital, 1000 Trancas Street, Napa, CA 94558.	941243669	12/05/2006	CA.	
Dana-Farber Cancer Institute, 44 Binney Street, Boston, MA 02115.	220162	12/05/2006	MA.	
Holmes Regional Medical Center, 1350 South Hickory Street, Melbourne, FL 32901.	100019	12/05/2006	FL.	
Niagara County PET Center, Niagara Falls, NY 14302	f27482	12/05/2006	NY	621 Tenth Street Department of Radiology.
Augusta Medical Center, 78 Medical Center Drive, Fishersville, VA 22939.	490018	12/05/2006	VA.	
Nevada Cancer Center, 2851 North Tenaya Way, Las Vegas, NV 89128.	VWQBHJ	12/05/2006	NV	#100.

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Wellstar Kennestone Hospital Imaging Center, 340 Kennestone Hospital Boulevard, Marietta, GA 30060.	110035	12/05/2006	GA	Suite LL10.
Ashtabula County Medical Center, 2412 Lake Avenue, Ashtabula, OH 44004.	1285607416	12/05/2006	OH	The Regional Cancer Center.
Rowan Regional Medical Center, 514 Corporate Circle, Salisbury, NC 28147.	340015	12/05/2006	NC.	
The Pottsville Hospital and Warne Clinic, 420 South Jackson Street, Pottsville, PA 17901.	390030	12/05/2006	PA.	
Georgetown Memorial Hospital, 606 Blackriver Road, Georgetown, SC 29442.	1982604021	12/05/2006	SC.	
Medical Center of Arlington, 3301 Matlock Road, Arlington, TX 76015.	450675	12/05/2006	TX.	
Valley View Regional Hospital, 430 N. Monte Vista, Ada, OK 74820.	370020	12/05/2006	OK.	
Montgomery Medical Services, 644 Maysville Road, Suite 10, Mount Sterling, KY 40353.	9141	12/05/2006	KY.	
Medical Outsourcing Services, LLC, 5409 N. Knoxville Avenue, Peoria, IL 61614.	211224	12/05/2006	IL.	
Medical Outsourcing Services, LLC, 1300 N. Main Street, Rushville, IN 46173.	223260	12/05/2006	IN.	
Mayo Clinic Arizona, 13400 E. Shea Boulevard, Scottsdale, AZ 85259.	WCTGB	12/05/2006	AZ.	
Door County Memorial Hospital, 323 S. 18th Avenue, Sturgeon Bay, WI 54235.	1093743874	12/05/2006	WI.	
Center for Diagnostic Imaging—Sartell, 166 19th Street S., Sartell, MN 56377.	C01307	12/05/2006	MN	Suite 100.
South Texas Institute of Cancer, 1205 South 19th Street, Corpus Christi, TX 78405.	0065AZ	12/05/2006	TX.	
Del Sol Medical Center, 10460 Vista Del Sol, El Paso, TX 79925.	450646	12/05/2006	TX.	
University Hospital, 818 St. Sebastian Way, Augusta, GA 30901	110028	12/05/2006	GA	Suite 103.
St. John Health System—Tulsa, OK, 1923 S. Utica Avenue, Tulsa, OK 74104.	370114	12/05/2006	OK.	
Allen Memorial Hospital, 1825 Logan Avenue, Waterloo, IA 50703.	160110	12/05/2006	IA.	
Craig General Hospital, 735 North Foreman Street, Vinita, OK 74301.	370065	12/05/2006	OK.	
Vision Imaging of Kingston, 517 Pierce Street, Kingston, PA 18704.	86463	12/05/2006	PA.	
Lake Hospital Mentor Campus, 9485 Mentor Avenue, Mentor, OH 44060.	360098	12/05/2006	OH	Attn:, Suite A.
Excela RCL PET CT Imaging, LLC, 200 Village Drive, Greensburg, PA 15601.	1144260415	12/05/2006	PA.	
Kousay Al-Kourainy, MD, 5395 Ruffin Road #202, San Diego, CA 92123.	A39783	12/05/2006	CA.	
Memorial Hermann Northwest Hospital, 1635 North Loop West, Houston, TX 77008.	450184	12/05/2006	TX.	
Accu/Site PET/CT Imaging Center, 30 Harrison Street, Johnson City, NY 13790.	DD1474	12/05/2006	NY	Suite #102.
DDIS—Bond, 9 Bond Street, Brooklyn, NY 11201	687s41	12/05/2006	NY.	
West Valley Radiology Medical Group, 7301 Medical Center Drive, West Hills, CA 91307.	Hw5870A	12/05/2006	CA	Suite 103.
Westside Diagnostic and Therapeutic Medical Center, LLC, 12524 West Washington Boulevard, Los Angeles, CA 90066.	TG472	12/05/2006	CA.	
DDIS—Still, 1783 Stillwell Avenue, Brooklyn, NY 11223	687s41	12/05/2006	NY.	
Alpena Regional Medical Center, 1501 W. Chisholm Street, Alpena, MI 49707.	386000029	12/05/2006	MI.	
Santa Monica Imaging Center, 1245 16th Street, Suite 105, Santa Monica, CA 90404.	1881670248	12/05/2006	CA.	
Mercer County Community Hospital, 800 W. Main Street, Coldwater, OH 45828.	360058	12/05/2006	OH.	
Johnson Memorial Hospital, 1125 W. Jefferson Street, Franklin, IN 46131–2675.	150001	12/05/2006	IN	PO Box 549.
St. Mary's Health Center, 100 St. Mary's Medical Plaza, Jefferson City, MO 65101.	260011	12/05/2006	MO.	
Eastside PET Center, LLC, 46 Medical Park East Drive, Birmingham, AL 35023.	1619925070	12/05/2006	AL	Suite 224.
United Regional Health Care System, 1600 8th Street, Wichita Falls, TX 76301.	450010	12/05/2006	TX.	
Denton Regional Medical Center, 3535 S. I–35, Denton, TX 76210.	450634	12/05/2006	TX.	
Canton-Potsdam Hospital, 50 Leroy Street, Potsdam, NY 13676	161012691	12/05/2006	NY.	
St. John Macomb Hospital, 11800 E. 12 Mile Road, Warren, MI 48093.	230195	12/05/2006	MI.	

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Cleveland Regional Medical Center, 201 East Grover Street, Shelby, NC 28150.	340021	12/05/2006	NC.	
Bluefield Regional Medical Center, 500 Cherry Street, Bluefield, WV 24701.	510071	12/05/2006	WV.	
Charles Cole Memorial Hospital, 1001 East Second Street, Coudersport, PA 16915.	390246	12/05/2006	PA.	
New Jersey State Open MRI, 155 State Street, Hackensack, NJ 07601.	85238	12/06/2006	NJ.	
Westcoast Radiology, 501 S. Lincoln Ave., Clearwater, FL 33756.	E4187	12/06/2006	FL.	
The Iowa Clinic/PETCO, LLC, 1221 Pleasant Street, Des Moines, IA 50309.	I5819	12/06/2006	IA.	
Quantum PET—Holy Spirit Hospital, 890 Poplar Church Road, Camp Hill, PA 17011.	40635	12/06/2006	PA.	
Coastal Bend PET Scan, Ltd., 1533 5th Street, Corpus Christi, TX 78404.	FTN014	12/06/2006	TX.	
Pottstown Memorial Medical Center, 1600 E. High Street, Pottstown, PA 19464.	390123	12/06/2006	PA.	
UTMB PET/CT Imaging Center, UTMB—Rebecca Sealy Hospital, Galveston, TX 77555–0793.	R518	12/06/2006	TX	301 University Blvd.
Diagnostic Imaging Services, LLC, 11110 Medical Campus Road, Suite 204, Hagerstown, MD 21742.	1114982808	12/06/2006	MD.	
North Memorial Medical Center, 3435 West Broadway, Robbinsdale, MN 55422.	1851344907	12/06/2006	MN.	
Hays Medical Center, 2220 Canterbury Drive, Hays, KS 67601	2473	12/06/2006	KS.	
St. Patrick Hospital & Health Sciences Center, 500 West Broadway, Missoula, MT 59802.	1023032588	12/06/2006	MT.	
Park Ridge Hospital, 100 Hospital Drive, Hendersonville, NC 28792.	340023	12/06/2006	NC.	
Fostoria Community Hospital, 610 Plaza Drive, Fostoria, OH 44830.	361318	12/06/2006	OH.	
UMDNJ—University Hospital, 30 Bergen Street, Newark, NJ 07101.	221775306	12/06/2006	NJ	ADMC 5 Room 575 P.O. Box 1709.
Metabolic Imaging of Boca, 5458 Town Center Road, Suite 103, Boca Raton, FL 33486.	E5434	12/06/2006	FL.	
Olean Open MRI, 413 North 8th Street, Olean, NY 14760	AA0996	12/06/2006	NY.	
Mercy Memorial Health Center, 1011 14th Avenue NW, Ardmore, OK 73401.	731500629	12/06/2006	OK.	
Pontiac Osteopathic Hospital d.b.a. POH Medical Center, 385 N. Lapeer Road, Oxford, MI 48371.	230207	12/06/2006	MI.	
Texas Oncology Ft. Worth, 1450 8th Avenue, Fort Worth, TX 76104.	00R66C	12/06/2006	TX.	
West Valley Imaging, 3025 S. Rainbow Boulevard, Las Vegas, NV 89146.	WQBDY	12/06/2006	NV.	
Springman Medical Plaza Imaging Center, PO Box 4650, Brownsville, TX 78523.	1912973108	12/06/2006	TX.	
EMH Regional Health Care System, 630 East River Street, Elyria, OH 44035.	360145	12/06/2006	OH.	
Denfeld Medical Center, 4702 Grand Avenue, Duluth, MN 55807.	C06028	12/06/2006	MN.	
Caldwell Memorial Hospital, 321 Mulberry Street SW, Lenoir, NC 28645.	560554202	12/06/2006	NC.	
Belleville, IL (Swansea), 4253 Argosy Court, Madison, WI 53714.	208196	12/06/2006	WI.	
Comprehensive Cancer Centers of Nevada—NW Office, 7445 Peak Drive, Las Vegas, NV 89128.	WCHCX	12/06/2006	NV.	
Wheaton Francisan Healthcare—St. Joseph, 5000 W. Chambers Street, Milwaukee, WI 53210.	520136	12/06/2006	WI.	
United Hospital Center, Rt. 19 South, Clarksburg, WV 26302–1680.	510006	12/06/2006	WV	#3 Hospital Plaza.
Massena Memorial Hospital, 1 Hospital Drive, Massena, NY 13662.	330223	12/06/2006	NY.	
Redlands Community Hospital, 350 Terracina Boulevard, Redlands, CA 92373.	ZZZ01782Z	12/06/2006	CA.	
The Valley Hospital, 1 Valley Health Plaza, Paramus, NJ 07652	310012	12/06/2006	NJ.	
Advanced Medical Imaging of Toms River, 1430 Hooper Avenue, Toms River, NJ 08753.	447655	12/06/2006	NJ	Suite 102.
McKenna Memorial Hospital, 598 N. Union Street, New Braunfels, TX 78130.	450059	12/06/2006	TX.	
NSMS—Parkland Farmington, Mo, 4253 Argosy Court, Madison, WI 53714.	208196	12/06/2006	WI.	
Alton Memorial Hospital, 1 Memorial Drive, Alton, IL 62002	14002	12/06/2006	IL.	
Medical City Dallas Hospital, Diagnostic Imaging, Dallas, TX 75230.	20943901	12/06/2006	TX	7777 Forest Lane.

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Mercy Medical Center, 301 St. Paul Place, Baltimore, MD 21202.	210008	12/06/2006	MD.	
St. Joseph's Medical Center, 503 N. 3rd Street, Brainerd, MN 56401.	240075	12/06/2006	MN.	
Covenant Healthcare, 600 Irving Street, Saginaw, MI 48602	1457354318	12/06/2006	MI.	
Little Company of Mary Hospital, 2800 West 95th Street, Evergreen Park, IL 60805.	140179	12/06/2006	IL.	
Marion General Hospital Progressive Medical Imagine, 830 N. Theatre Drive, Marion, IN 46952.	1457354318	12/06/2006	IN.	
Escondido Pulmonary Medical Group, 5395 Ruffin Road, Suite 202, San Diego, CA 92123.	W301	12/06/2006	CA.	
Marshall Medical Center, 1100 Marshall Way, Placerville, CA 95667.	50254	12/06/2006	CA.	
Clermont Radiology, 1804 Oakley Seaver Drive, Clermont, FL 34711.	U5066	12/06/2006	FL	Suite B.
Mahoning Valley Imaging, Ltd., 7067 Tiffany Boulevard, Youngstown, OH 44514.	1457354318	12/06/2006	OH.	
Southeastern Ohio Regional Medical Center, 1341 Clark Avenue, Cambridge, OH 43725.	1457354318	12/06/2006	OH.	
White County Medical Center, 3214 E. Race Avenue, Searcy, AR 72143.	40014	12/06/2006	AR.	
MED Arts JVIC, 9101 Franklin Square Drive, Baltimore, MD 21237.	1932167178	12/06/2006	MD.	
Memorial Hermann Southwest OPID, 7797 SW Freeway, Houston, TX 77074.	741152597	12/06/2006	TX.	
Twin County Regional Hospital, 200 Hospital Drive, Galax, VA 24333.	1174524094	12/06/2006	VA.	
Marion Ancillary Services, LLC, 1040 Delaware Avenue, Marion, OH 43302.	991	12/06/2006	OH.	
Owensboro Medical Health Systems, Breckenridge Diagnostics, Owensboro, KY 42301.	180038	12/06/2006	KY	1020 Breckenridge Street.
NSMS—Darlington, WI, 209 Limestone Pass, Cottage Grove, WI 53527.	92420	12/06/2006	WI.	
Santa Fe Imaging, LLC, 1640 Hospital Drive, Santa Fe, NM 87505.	400521037	12/06/2006	NM.	
Suncoast Imaging of Port Orange, 1680 Dunlawton Avenue, Port Orange, FL 32127.	40370B	12/06/2006	FL.	
Great Basin Imaging, 2874 N Carson Street, 3rd Floor, Carson City, NV 89706.	WJBDK	12/06/2006	NV.	
St. Francis Hospital & Health Centers, 1201 Hadley Road, Mooresville, IN 46158.	1457354318	12/06/2006	IN.	
Las Colinas Cancer Center, 7415 Las Colinas Boulevard, Irving, TX 75063.	00J062	12/06/2006	TX.	
ADI, 4006 Jonathan Street, Waterloo, IA 50701	I15454	12/06/2006	IA.	
St. Francis Hospital & Health Centers South, 8111 S. Emerson Avenue, Indianapolis, IN 46237.	1457354318	12/06/2006	IN.	
Central Baptist Diagnostic Center, 100 Southland Drive, Lexington, KY 40503.	9375001	06/14/2006	KY	Suite B.
Baptist Health Medical Center—NLR PET/CT, 3500 Springhill Drive, North Little Rock, AR 72117.	5F437	05/03/2007	AR	Suite 100.
Commonwealth Hematology Oncology, 216 Southtown Drive, Danville, KY 40422.	1285687178	03/21/2007	KY.	
Commonwealth Hematology Oncology, 95 Bogle Office Park Drive, Somerset, KY 42503.	1285687178	03/21/2007	KY.	
UMPC and The Washington Hospital Cancer Center, 155 Wilson Avenue, Washington, PA 15301.	105589VXB	03/10/2006	PA.	
Lexington Diagnostic Center, 1725 Harrodsburg Road, Suite 100, Lexington, KY 40504.	0406	03/08/2006	KY.	
UW PET Imaging Center, 8007 Excelsior Drive, Madison, WI 53717.	1346266319	04/03/2007	WI.	
Fort Wayne Medical Oncology and Hematology, 7910 W. Jefferson Boulevard, Suite 107, Ft. Wayne, IN 46804.	055770	04/23/2007	IN.	
Danbury Hospital, 24 Hospital Avenue, Danbury, CT 06810	070033	04/23/2007	CT.	
Reno Diagnostic Centers, 590 Eureka Avenue, Reno, NV 89512.	1518904994	04/24/2007	NV.	
The Kirklin Clinic PET-CT Facility, 2000 6th Ave South, Birmingham, AL 35233.	10933768723	05/07/2007	AL.	
PET Imaging Radiology, PSC Paseo San Pablo 100, Bayamon, PR.	0085142	05/15/2007	PR	EDIF Dr. Arturo Cadilla, Suite 208.
Punxsutawney Area Hospital, 81 Hillcrest Drive, Punxsutawney, PA 15767.	390199	05/15/2007	PA.	
Princeton Baptist Medical Center, 701 Princeton Avenue SW, Birmingham, AL 35211.	35211	05/30/2007	AL.	

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Medical Arts Radiology Commack, 55 Veterans Memorial Highway, Commack, NY 11725.	W11682	05/31/2007	NY.	
Carrol, Sheth & Raghavan, MD, 1460 Bluegrass Avenue, Louisville, KY 40215.	5460	06/05/2007	KY.	
Personal Care Molecular Imaging, 1514 Highway 138, Wall, NJ 07719.	109631	06/06/2007	NJ.	
Lincoln Radiology Imaging, 7121 Stephanie Lane, Lincoln, NE 68516.	099920	06/06/2007	NE.	
Medcenter One, 300 North 7th Street, Bismark, ND 58506–5525.	1538245634	07/24/2007	ND.	
Wheaton Franciscan Healthcare—All Saints, 3801 Spring Street, Racine, WI 53405.	520096	08/08/2007	WI	N/A.
Diagnostic Centers of America, 6080 Boynton Boulevard, Suite 140, Boynton Beach, FL 33437.	E4439	08/22/2007	FL	N/A.
Center for Integrative Cancer Medicine, P.A, 1733 Curie Drive, Suite 305, El Paso, TX 79902.	00315U	08/22/2007	TX	N/A.
St. Luke's Hospital, 1026 A Avenue N.E., Cedar Rapids, IA 52406–3026.	160045	08/22/2007	IA	N/A.
Shared PET Imaging, LLC—Cincinnati OH, Eden Avenue & Albert Sabin Way, Cincinnati, OH 45219.	ID01511	08/22/2007	OH	N/A.
Integrated Magnetic Imaging, 7100 University Court, Montgomery, AL 36117.	7811	08/22/2007	AL	N/A.
Northwest PET Imaging, 265 N. Broadway Street, Portland, OR 97227.	105512	08/22/2007	OR	N/A.
Center for Diagnostic Imaging—St. Louis Park, 5775 Wayzata Boulevard #190, St. Louis Park, MN 55416.	C01307	08/22/2007	MN	N/A.
Ponca City Medical Center, 1900 North 14th Street, Ponca City, OK 74601.	370006	08/22/2007	OK	N/A.
Sanford Health, 1305 W. 18th Street, Sioux Falls, SD 57117	430027	08/22/2007	SD	N/A.
Central Valley PET Imaging, 4744 Quail Lake Drive, Stockton, CA 95207.	00A484230	08/22/2007	CA	N/A.
PET/CT Imaging Center, 4000 N. Illinois Lane, Swansea, IL 62226.	201339	08/22/2007	IL	PET/CT Imaging Center.
Memorial Medical Center, 1105 W. Frank Avenue, Suite 100, Lufkin, TX 75901.	450211	08/22/2007	TX	d.b.a. Temple Imaging Center.
Rockingham Memorial Hospital, 235 Cantrell Ave, Harrisonburg, VA 22801.	490004	08/22/2007	VA	N/A.
Regions Imaging Center, 401 Phalen Boulevard, 41101C, St. Paul, MN 55101.	240106	08/22/2007	MN	N/A.
Florida Hospital Imaging, LLC, 335 Clyde Morris Boulevard, Suite 250, Ormond Beach, FL 32174.	1104876358	08/22/2007	FL	N/A.
Hutchinson Clinic, PA, 2101 North Waldron Street, Hutchinson, KS 67502.	1043298474	08/22/2007	KS	N/A.
Parkwest Imaging, 3676 Parker Boulevard, Pueblo, CO 81008	455838	08/22/2007	CO	N/A.
St. Clair Hospital/UPMC Cancer Center PET/CT, 1000 Bower Hill Road, Pittsburgh, PA 15243.	1699708792	08/22/2007	PA	N/A.
St. Joseph Mercy Oakland (SJMO), 44405 Woodward Avenue, Pontiac, MI 48341.	1457354318	08/22/2007	MI	N/A.
Edward Hospital, 801 S. Washington Street, Naperville, IL 60540.	140231	08/22/2007	IL	N/A.
East Montgomery Imaging Center, 6880 Winton Blount Boulevard, Montgomery, AL 36117.	58866	08/22/2007	AL	N/A.
Memorial Hospital of Martinsville and Henry County, 320 Hospital Drive, Martinsville, VA 24112.	490079	08/22/2007	VA	N/A.
Thomas Hospital, 750 Morphy Avenue, Fairhope, AL 36532	10100	08/22/2007	AL	N/A.
Portland Adventist Medical Center, 10123 SE Market Street, Portland, OR 97216.	380060	08/22/2007	OR	N/A.
Nash Healthcare System, Inc., 2460 Curtis Ellis Drive, Rocky Mount, NC 27804.	340147	08/22/2007	NC	N/A.
North Broward Medical Center, 201 E. Sample Road, Deerfield Beach, FL 33064.	100068	08/22/2007	FL	Radiology.
Jennie Stuart Medical Center, 320 West 18th Street, Hopkinsville, KY 42240.	180051	08/22/2007	KY	N/A.
Greater Houston Imaging, L.P., 6565 West Loop South, Suite 100, Bellaire, TX 77401.	FTNPX1	08/22/2007	TX	N/A.
Sunrise Hospital Medical Center, 3186 South Maryland Parkway, Las Vegas, NV 89109.	290003	08/22/2007	NV	N/A.
The Diagnostic and Treatment Center, 3401 Cranberry Boulevard, Weston, WI 54476.	92450	08/22/2007	WI	N/A.
Ochsner Medical Center, 1514 Jefferson Highway, New Orleans, LA 70121.	720502505	08/22/2007	LA	N/A.
Inland Empire Medical Imaging, 225 W. Hospitality Lane, Suite #100, San Bernardino, CA 92408.	zzz316682	08/22/2007	CA	N/A.

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Independent Nuclear PET Imaging, 1115 N. Parrott Avenue, Okeechobee, FL 34972.	1922070796	08/22/2007	FL	N/A.
Hugh Chatham Memorial Hospital, 180 Parkwood Drive, Elkin, NC 28621.	340097	08/22/2007	NC	N/A.
Marian Medical Center/Plaza Diagnostic Imaging, 525 E. Plaza Drive, Santa Maria, CA 93454.	50107	08/22/2007	CA	N/A.
DDIS—FH, 8002 Kew Gardens Road, Kew Gardens, NY 11415	687s41	08/22/2007	NY	N/A.
NYPH—Weill Cornell, 525 E 68th Street, New York, NY 10021	131623978	08/22/2007	NY	N/A.
Genesys Regional Medical Center, One Genesys Parkway, Grand Blanc, MI 48439–8066.	230197	08/22/2007	MI	N/A.
Geisinger Medical Center, 100 North Academy Avenue, Danville, PA 17822.	390006	08/22/2007	PA	N/A.
Citrus Diagnostic Center, 922 N Citrus Avenue, Crystal River, FL 34428.	K5374	08/22/2007	FL	N/A.
Middlesex Hospital, 534 Saybrook Road, Middletown, CT 06457	70020	08/22/2007	CT	N/A.
Geisinger Wyoming Valley Medical Center, 1000 East Mountain Drive, Wilkes-Barre, PA 18711.	390270	08/22/2007	PA	N/A.
Canton, IL—Northern Shared Medical Services, 209 Limestone Pass, Cottage Grove, WI 53527.	208196	08/22/2007	WI	N/A.
Self Regional Healthcare, 102 Academy Street, Greenwood, SC 29646.	420071	08/22/2007	SC	N/A.
Bristol Hospital, Brewster Road, Bristol, CT 06011	70029	08/22/2007	CT	P.O. Box 977.
East Texas Hematology & Oncology Clinic, PA, 1202 West Frank Avenue, Lufkin, TX 75904.	00T37K	08/22/2007	TX	N/A.
St. John River District Hospital, 4100 River Road, East China, MI 48054.	230241	08/22/2007	MI	N/A.
Morgan Hospital, 2209 John R Wooden Drive, Martinsville, IN 46151.	150038	08/22/2007	IN	N/A.
Cotton-O'Neil Cancer Center, 1414 SW 8th Street, Topeka, KS 66606.	1811944457	08/22/2007	KS	N/A.
Barnes-Jewish West County Hospital, 12634 Olive Boulevard, St. Louis, MO 63141.	260162	08/22/2007	MO	N/A.
Hardin Memorial Hospital, 913 North Dixie Avenue, Elizabethtown, KY 42701.	180012	08/22/2007	KY	N/A.
Cancer Institute of Florida, LLC, 894 E. Altamonte Drive, Altamonte Springs, FL 32701.	72793	08/22/2007	FL	N/A.
Community Hospital, New Port Richey, 5637 Marine Parkway, New Port Richey, FL 34652.	100191	08/22/2007	FL	N/A.
Pulaski Community Hospital, 2400 Lee Highway, Pulaski, VA 24301.	490116	08/22/2007	VA	N/A.
Advocate South Suburban Hospital, 17800 S. Kedzie Avenue, Hazel Crest, IL 60429.	3.62169E+11	08/22/2007	IL	N/A.
St. Vincent's Medical Center, 2800 Main Street, Bridgeport, CT 06606.	70028	08/22/2007	CT	N/A.
Cayuga Medical Center at Ithaca, 3218 Wilkins Road, Ithaca, NY 14850.	330307	08/22/2007	NY	N/A.
Immanuel—St. Josephs Mayo Health Stystem, 1025 Marsh Street, Mankato MN 56002–8673.	240093	08/22/2007	MN	PO Box 8673.
Kell West Regional Hospital, 5420 Kell West Boulevard, Wichita Falls, TX 76310.	450827	08/22/2007	TX	N/A.
Aurora Medical Center Kenosha, 10400 75th Street, Kenosha, WI 53142.	520189	08/22/2007	WI	N/A.
Aurora Lakeland Medical Center, W3985 County Rd NN, Elkhorn, WI 53121.	520102	08/22/2007	WI	N/A.
Munson Medical Center, 1105 Sixth Street, Traverse City, MI 49684.	230097	08/22/2007	MI	N/A.
Kansas City Cancer Center—North, 8700 Greenhills Road, Kansas City, MO 64154.	5650000E	08/22/2007	MO	N/A.
PET Imaging Center of Maine, 885 Union Street, Suite 115, Bangor, ME 04401.	10211501	08/22/2007	ME	N/A.
SMS—Chester, IL, 1900 State Street, Chester, IL 62233	208196	08/22/2007	IL	N/A.
PET of Reston, LP, 1800 Town Center Drive, Suite 115, Reston, VA 20190.	G01960P03	08/22/2007	VA	N/A.
Healthcare Imaging Center, 4334 Central Ave, Riverside, CA 92506.	ZZZ14451Z	08/22/2007	CA	N/A.
Robert Wood Johnson University Hospital at Hamilton, 1 Hamilton Health Place, Hamilton, NJ 08690.	310110	08/22/2007	NJ	N/A.
Northside Hospital, 1000 Johnson Ferry Road, Atlanta, GA 30342.	110161	08/22/2007	GA	N/A.
Aurora Medical Center Kenosha, 10400 75th Street, Kenosha, WI 53142.	520189	08/22/2007	WI	N/A.
Partners Imaging Center of Sarasota, 1250 S. Tamiami Trail, Suite 103, Sarasota, FL 34239.	Q0353	08/22/2007	FL	N/A.

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Memorial Medical Center, 216 Sunset Place, Neillsville, WI 54456.	521323	08/22/2007	WI	N/A.
Central Virginia Imaging, LLC, 1900 Tate Spings Road, Suite 21, Lynchburg, VA 24501.	1578594412	08/22/2007	VA	N/A.
Los Alamitos Medical Center, 3951 Katella Ave, Los Alamitos, CA 90720.	50551	08/22/2007	CA	N/A.
Valley Advanced Imaging, LLC, 2403 Butler Street, Easton, PA 18042.	1417907023	08/22/2007	PA	N/A.
Good Samaritan PET/CT and Imaging services, 1245 Montauk Hwy, West Islip, NY 11795.	330286	08/22/2007	NY	N/A.
Scotland Memorial Hospital, 500 Lauchwood Drive, Laurinburg, NC 28352.	340008	08/22/2007	NC	N/A.
McFarland Clinic, P.C., 1111 Duff Avenue, Ames, IA 50010	1639135643	08/22/2007	IA	N/A.
Providence Hospital, 1150 Varnum Street NE, Washington, DC 20017.	90006	08/22/2007	DC	N/A.
The Angeles Clinic and Research Institute, 11818 Wilshire Boulevard, Suite 200, Los Angeles, CA 90025.	W15185A	08/22/2007	CA	N/A.
Rose Radiology Centers, Inc., 5107 N. Armenia Avenue, Tampa, FL 33603.	1629162904	08/22/2007	FL	Bldg B.
Texas Oncology East Houston, 13111 East Freeway, Houston, TX 77015.	1811944101	08/22/2007	TX	N/A.
NSMS—St. Joe's—Breese, IL, 9515 Holy Cross Lane, Breese, IL 62230.	208196	08/23/2007	IL	N/A.
UT Cancer Institute, 7945 Wolf River Boulevard, Germantown, TN 38138.	3711381	08/23/2007	TN	N/A.
Fresno Imaging Center, 6191 N. Rhesta Avenue, Fresno, CA 93710.	N/A.	08/23/2007	CA	N/A.
Imaging Consultants Inc. at Sturdy Memorial, 211 Park Street, Attleboro, MA 02703.	327085	08/23/2007	MA	N/A.
Fairfax PET Imaging Center, LLC, 8503 Arlington Boulevard Lower level, Fairfax, VA 22031.	1861433674	08/23/2007	VA	N/A.
City Hospital, Inc., 2500 Hospital Drive, Martinsburg, WV 25401	510008	08/23/2007	WV	N/A.
White Plains Radiology Associates PET Center, Davis and Post Roads, White Plains, NY 10601.	w11842	08/23/2007	NY	N/A.
Lenoir Memorial Hospital, 100 Airport Road, Kinston, NC 28503–1678.	1962446385	08/23/2007	NC	N/A.
Sand Lake Imaging, 9350 Turkey Lake Road, Orlando, FL 32819.	34896	08/23/2007	FL	Suite 100.
Advocate Lutheran General Center For Advanced Care, 1800 Luther Lane, Park Ridge, IL 60068.	140223	08/23/2007	IL	N/A.
Flower Hospital, 5200 Harroun Road, Sylvania, OH 43560	360074	08/23/2007	OH	N/A.
Dekalb Memorial Hospital, 1316 E. 7th Street, Auburn, IN 46706.	N/A.	08/23/2007	IN	N/A.
St. John Hospital and Medical Center, 1315 Macom Drive, Naperville, IL 60564.	116	08/23/2007	IL	N/A.
Bayhealth Medical Center, 540 S. Governors Avenue, Dover, DE 19904.	N/A.	08/23/2007	DE	N/A.
ImageCare, 713 Troy-Schenectady Road, Suite 124, Latham, NY 12110.	1922048370	08/23/2007	NY	Capital Region Health Park.
Southside Regional Medical Center, 801 South Adams Street, Petersburg, VA 23803.	490067	08/23/2007	VA	N/A.
East Alabama Medical Center—Auburn Diagnostic Imaging, 1527 Professional Parkway, Auburn, AL 36830.	29	08/23/2007	AL	N/A.
Trover Health System, 900 Hospital Drive, Madisonville, KY 42431.	1457354318	08/23/2007	KY	N/A.
Doctors Hospital at Renaissance, Ltd, 5501 S. McColl Road, Edinburg, TX 78359.	450869	08/23/2007	TX	N/A.
Twin Lakes Imaging Center, 1890 LPGA Boulevard, Daytona Beach, FL 32117.	1023040870	08/23/2007	FL	Suite 110.
Nathan Littauer Hospital, 99 E. State Street, Gloversville, NY 12078.	330276	08/23/2007	NY	N/A.
Altoona Regional Health System, 620 Howard Avenue, Altoona, PA 16601.	390073	08/23/2007	PA	N/A.
Warren General Hospital, 2 Crescent Park West, Warren, PA 16365.	390146	08/23/2007	PA	N/A.
Reid Hospital Health Care Services, 1401 Chester Boulevard, Richmond, IN 47374.	1457354318	08/23/2007	IN	N/A.
Orange City Area Health System, 1000 Lincoln Circle SE, Orange City, IA 51041.	161360	08/23/2007	IA	N/A.
Mercy Hospital Clermont, 3000 Hospital Drive, Batavia, OH 45103.	1457354318	08/23/2007	OH	N/A.
Arroyo Grande Community Hospital, 345 South Halcyon Road, Arroyo Grande, CA 93454.	50016	08/23/2007	CA	N/A.

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HealthEast St. John's Hospital, 1575 Beam Avenue, Maplewood, MN 55109.	240210	08/23/2007	MN	N/A.
St. Joseph's/Candler Health System, 5353 Reynolds Street, Savannah, GA 31405.	110024	08/23/2007	GA	N/A.
NSMS—Pickneyville, IL, 101 North Walnut Street, Pinckneyville, IL 62274.	208196	08/23/2007	IL	N/A.
Duke Raleigh Hospital, 3400 Wake Forrest Road, Raleigh, NC 27609.	340073	08/23/2007	NC	N/A.
Advanced Radiology Services & The Center for Women, 400 Plaza Court, East Stroudsburg, PA 18301.	33012	08/23/2007	PA	Suite C.
Community Hospital, 10020 Donald S. Powers Drive, Munster, IN 46321.	140125	08/23/2007	IN	N/A.
Avant Imaging—Woodland Health Center, 7575 Grand River Avenue, Brighton, MI 48114.	1457354318	08/23/2007	MI	N/A.
EVDI Medical Imaging—East Mesa, 6424 E. Broadway Road, Mesa, AZ 85206.	1164434098	08/23/2007	AZ	Suite 101.
NSMS—St. Louis, Mo—ARCH Medical, 209 Limestone Pass, Cottage Grove, WI 53527.	47013	08/23/2007	WI	N/A.
CNY PET LLC, 5100 West Taft Road, Liverpool, NY 13088	AA0672	08/23/2007	NY	Suite 2C.
MCMI, 3000 Telegraph Avenue, Oakland, CA 94609	ZZZ27496Z	08/23/2007	CA	N/A.
Green Clinic, LLC, 1200 S. Farmerville Street, Ruston, LA 71270.	57387	08/23/2007	LA	N/A.
Fayette Memorial Hospital, 3542 North Western Avenue, Connersville, IN 47331.	150064	08/23/2007	IN	N/A.
Carolinas Medical Center—Union, 600 Hospital Drive, Monroe, NC 28112.	340130	08/23/2007	NC	Nuclear Medicine Department.
Citrus Medical Imaging Associates, Inc., 1000 Lakes Drive, Suite 170, West Covina, CA 91790.	HW2326	08/23/2007	CA	N/A.
Radiation Oncology at WFUBMC, Radiation Oncology Medical Center Boulevard, Winston-Salem, NC 27152.	340047	08/24/2007	NC	Wake Forest University Baptist Medical Center Comprehensive Cancer Center.
Harrison County Hospital, 245 Atwood Street, Corydon, IN 47112.	151331	08/24/2007	IN	N/A.
Thibodaux Regional Medical Center, 602 North Acadia Road, Thibodaux LA 70301.	190004	08/24/2007	LA	N/A.
NSMS—Hot Springs, AR, 1600 Higdon Ferry Road, Hot Springs AR 71913.	5F168	08/24/2007	AR	N/A.
Pacific Oncology, PC, 15700 SW Greystone Court, Beaverton OR 97006.	1043262116	08/24/2007	OR	N/A.
Cancer Care Associates, 1791 E. Fir Avenue, Fresno, CA 93720.	222375652	08/24/2007	CA	N/A.
Massatusetts Mobile PET, PC—Newburyport, 25 Highland Avenue, Newburyport, MA 01950.	327086	08/24/2007	MA	N/A.
Hematology Oncology Associates of Illinois, 6801 West 34th Street, Berwyn, IL 60402.	218890	08/24/2007	IL	Suite 107.
Massatusetts Mobile PET, PC— Haverhill, 140 Lincoln Avenue, Haverhill, MA 01830.	327086	08/24/2007	MA	N/A.
Corinth Medical Group, 4851 I35 East, Suite 101, Corinth, TX 76210.	00K22X	08/24/2007	TX	N/A.
New England PET Imaging Manchester, One Elliot Way, Manchester, NH 03103.	327081	08/24/2007	NH	N/A.
The Surgery Clinic, 1026 Goodyear Avenue, Gadsden, AL 35999.	N/A	08/24/2007	AL	Suite B–101.
Boston Medical Center, 830 Harrsion Avenue, Boston, MA 02118.	220031	08/24/2007	MA	Suite 1600.
Mercy Health Center, 4190 24th Avenue, Fort Gratiot, MI 48059	1457354318	08/24/2007	MI	N/A.
The Cancer Center of Santa Barbara, 300 W. Pueblo Street, Santa Barbara, CA 93105.	W13890	08/24/2007	CA	N/A.
Milford Memorial Hospital Bayhealth Medical Center, 21 W. Clarke Avenue, Milford, DE 19963.	N/A	08/24/2007	DE	N/A.
North Coast Cancer Care, 417 Quarry Lakes Drive, Sandusky, OH 44870.	NO9915215	08/24/2007	OH	N/A.
Palm Beach Gardens Open Imaging Center, 3335 Burns Road #101, Palm Beach Gardens, FL 33408.	U8767	08/24/2007	FL	N/A.
Advanced Medical Imaging, LLC, 1780 NW Myhre Road, Silverdale, WA 98383.	AB24179	08/24/2007	WA	Suite 1220.
Swedish American Hospital, 1401 E State Street, Rockford, IL 61104.	140228	08/24/2007	IL	N/A.
Molecular Diagnostics of Eastern Omaha, 117 North 32nd Avenue, Suite 100, Omaha, NE 68131.	99894	08/24/2007	NE	N/A.
Kingwood Medical Center, 22999 U.S. Hwy 59, Kingwood, TX 77339.	1811942238	08/24/2007	TX	N/A.

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Health Village Imaging, 1301 Route 72 West, Manahawkin, NJ 08050.	1194810978	08/24/2007	NJ	Suite 100.
ARH Hazard, 100 Medical Center Drive, Hazard, KY 41701	520795508	08/24/2007	KY	N/A.
Central Florida Imaging Center, Inc., 6801 US 27 N, Suite E–3, Sebring, FL 33870.	1427076769	08/24/2007	FL	N/A.
West Texas Cancer Center, 301 N Washington Avenue, Odessa, TX 79761.	00543K	08/24/2007	TX	N/A.
Beloit Memorial Hospital, 1969 West Hart Road, Beloit, WY 53511.	520100	08/24/2007	WY	N/A.
Pinnacle Imaging Center, 2390 NW 7th Street, Miami, FL 33125	U5131	08/24/2007	FL	Suite 103.
PET Imaging of El Paso, 1225 E. Cliff Drive, El Paso, TX 79902	FTN035	08/24/2007	TX	Building 3, Suite 200.
St. Petersburg General Hospital, 6500 38th Avenue North, St. Petersburg, FL 33710.	N/A	08/24/2007	FL	N/A.
St. Mary Medical Center, 1201 Langhorne-Newtown Road, Langhorne, PA 19047.	390258	08/24/2007	PA	N/A.
St. Joseph Medical Center, 1401 St. Joseph Parkway, Houston, TX 77002.	1154361475	08/24/2007	TX	N/A.
UPMC Northwest, 1671 Allegheny Boulevard, Reno, PA 16343	390091	08/24/2007	PA	N/A.
Mercy Hospital Fairfield, 3000 Mack Road, Fairfield, OH 45014	1457354318	08/24/2007	OH	N/A.
Radiology Associates of West Pasco, 5539 Marine Parkway, New Port Richey, FL 34652.	1558328963	08/24/2007	FL	N/A.
St. Dominic Hospital, 969 Lakeland Drive, Jackson, MS 39216	250048	08/24/2007	MS	N/A.
RCOA—Adventist Health—Sequoia, 4949 W. Cypress Avenue, Visalia, CA 93271.	1427198696	08/24/2007	CA	N/A.
McKee Medical Center, 2000 Boise Ave, Loveland, CO 80538 ..	60030	08/24/2007	CO	N/A.
Bon Secours Richmond Community Hospital, 1500 North 28th Street, Richmond, VA 23223.	490094	08/24/2007	VA	N/A.
West Houston Medical Center, 12141 Richmond Avenue, Houston, TX 77082.	450644	08/24/2007	TX	N/A.
Shands Teaching Hospital and Clinics, Inc., 2000 SW Archer Road, Gainesville, FL 32608.	100113	08/24/2007	FL	Radiology, Shands Medical Plaza.
Tanner Medical Center, 119 Ambulance Drive, Carrollton, GA 30117.	110011	08/24/2007	GA	N/A.
OU Medical Center, 700 NE 13th Street, Oklahoma City, OK 73104.	1780631390	08/24/2007	OK	N/A.
The Medical Center of Aurora, 1400 S. Potomac Street, Aurora, CO 80012.	60100	08/24/2007	CO	#180.
AllenRidge Diagnostic Imaging Center, 520 Lecanto Highway, Lecanto, FL 34461.	100023	08/24/2007	FL	N/A.
The PET Center at BWMC, 305 Hospital Drive, Baltimore, MD 21061.	1124016696	08/24/2007	MD	SUITE 302.
Signet Diagnostic Imaging Services, LLC, 8300 West Sunrise Boulevard, Plantation, FL 33322.	E8667	08/24/2007	FL	N/A.
Adams Diagnostic Imaging, 20 Expedition Trail, Gettysburg, PA 17325.	65290	08/24/2007	PA	Suite 102.
Jennie Edmundson Hospital, 933 E. Pierce Street, Council Bluffs, IA 51503.	160047	08/24/2007	IA	N/A.
Holy Cross Hospital, 4725 N. Federal Highway, Fort Lauderdale, FL 33308.	100073	08/24/2007	FL	Bienes Diagnostic Imaging Center.
Medical University of Ohio, 3000 Arlington Avenue, Toledo, OH 43614.	1457354318	08/24/2007	OH	N/A.
Daviess Community Hospital, 1314 E Walnut Street, Washington, IN 47501.	150061	08/24/2007	IN	Radiology Department.
Jeff Anderson Regional Medical Center, 2124 14th Street, Meridian, MS 39301.	250104	08/24/2007	MS	N/A.
Modesto Imaging Center, 157 E. Coolidge Avenue, Modesto, CA 95350.	ZZZ01977Z	08/24/2007	CA	N/A.
Sioux Center Commmunity Hospital and Health Center, 605 South Main Ave, Sioux Center, IA 51250.	161346	08/24/2007	IA	N/A.
Southern Ohio Medical Center, 1121 Kinneys Lane, Portsmouth, OH 45662.	360008	08/24/2007	OH	N/A.
Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114.	220071	08/24/2007	MA	N/A.
Clinton Memorial Hospital Regional Health System, 31 Farquhar Avenue, Wilmington, OH 45177.	316005307	08/24/2007	OH	N/A.
CJW Medical Center, 1401 Johnston Willis Drive, Richmond, VA 23235.	34632	08/24/2007	VA	N/A.
Texas Oncology Weatherford, 907 Foster Lane, Weatherford, TX 76086.	00539K	08/24/2007	TX	N/A.
Sharper Imaging Diagnostic Radiology Center, 3430 Tamiami Trail, Port Charlotte, FL 33952.	1730288515	08/24/2007	FL	Suite B.
Morristown—Hamblin Healthcare System, 908 W. 4th N. Street, Morristown, TN 37814.	1457354318	08/24/2007	TN	N/A.

Facility name	Provider number	Date approved	State	Other information
Puget Sound PET Imaging, 6808 220th Street SW, Mountlake Terrace, WA 98043.	115162600	08/24/2007	WA	Suite 150.
Detar Hospital Navarro, 506 E. San Antonio Street, Victoria, TX 77902.	450147	08/24/2007	TX	N/A.
PET Imaging of Chicago, 6801 West 34th Street, Suite 105Berwyn, IL 60402.	214832	08/24/2007	IL	N/A.
Imaging Specialists Group, Ltd., 3101 Churchill Road, Flower Mound, TX 75022.	1417991852	08/24/2007	TX	Suite 100.
OKOmed Downtown Imaging, 2101 Crawford Street, Suite 115, Houston, TX 77002.	1780622464	08/24/2007	TX	N/A.
Clear Lake Regional Medical Center, 500 Medical Center Boulevard, Webster, TX 77598.	1063466035	08/24/2007	TX	N/A.
Norton Hospital, 315 East Broadway, Louisville, KY 40202	180088	08/24/2007	KY	N/A.
Saratoga PET Associates, LLC, 3 Emma Lane, Clifton Park, NY 12065.	1356357172	08/24/2007	NY	N/A.
Genesis Health Care System, 2800 Maple Avenue, Zanesville, OH 43701.	1457354318	08/24/2007	OH	N/A.
Lake Cumberland Regional Hospital, 27 Imaging Drive, Somerset, KY 42503.	1457354318	08/24/2007	KY	N/A.
Saint Francis Cancer Institute, 14 Doctors' Park, Cape Girardeau, MO 63703.	260183	08/24/2007	MO	N/A.
American Health Network of IN, LLC—PET/CT, 6820 Parkdale Place, Indianapolis, IN 46254.	1164491775	08/24/2007	IN	Suite #105.
PET CT Nuclear Radiology, Inc., 1501 Edisicio Detantacourt, Suite 302, Fernadez Juncos Santorze, PR 909.	57886	08/24/2007	PR	Fernadez Juncos Santorze.
NSMS—Reedsburg, WI, 2000 North Dewey Street, Reedsburg, WI 53959.	1295785079	08/24/2007	WI	N/A.
Wayne Memorial Hospital, 2700 Wayne Memorial Hospital, Goldsboro, NC 27534.	340010	08/24/2007	NC	N/A.
InMed Diagnostic Services of IL, 10419 Fleming Road, Carterville, IL 62918.	205040	08/24/2007	IL	N/A.
Henrico Doctors' Hospital, 1602 Skipwith Road, Richmond, VA 23229.	490118	08/24/2007	VA	N/A.
Alliance Imaging—United General Hospital, 2000 Hospital Drive, Sedro Woolley, WA 98284.	8862377	08/24/2007	WA	N/A.
Spencer Municipal Hospital, 1200 First Avenue East, Spencer, IA 51301.	1255328621	08/24/2007	IA	N/A.
Radilogy LTD LaCholla Center—Diagnostic Imaging, 5960 N. LaCholla Avenue, Tucson, AZ 85704.	1841261989	08/24/2007	AZ	N/A.
Saint Elizabeth Regional Medical Center, 555 South 70th Street, Lincoln, NE 68510.	280020	08/24/2007	NE	N/A.
Bucyrus Community Hospital, 629 N. Sandusky Avenue, Bucyrus, OH 44820.	361316	08/24/2007	OH	N/A.
Mercy Hospital of Willard, 110 E. Howard Street, Willard, OH 44890.	361310	08/24/2007	OH	N/A.
Lower Columbia Pathologists, 1606 East Kessler Boulevard, Longview, WA 98632.	745800	08/24/2007	WA	4th Floor.
Newton Medical Center, 600 Medical Center Drive, Newton, KS 67114.	170103A	08/24/2007	KS	N/A.
Advanced Imaging Partners, 508 Cleveland Street, Great Bend, KS 67530.	1295791325	08/24/2007	KS	N/A.
Integrated Medical Imaging, 1040 Greenwood Springs Boulevard, Greenwood, IN 46143.	221970	08/24/2007	IN	N/A.
Avera Sacred Heart Cancer Center, 501 Summit Street, Yankton, SD 57078.	430012	08/24/2007	SD	N/A.
ValleyCare Medical Center, 5555 W. Las Positas Boulevard, Pleasanton, CA 94588.	50283	08/24/2007	CA	N/A.
NSMS—Mena, AR, 311 North Morrow Street, Mena, AR 71953	1295785079	08/24/2007	AR	N/A.
Memorial Hospital Easton, 219 S. Washington Street, Easton, MD 21601.	210037	08/24/2007	MD	N/A.
Seattle Cancer Care Alliance, 825 Eastlake Avenue E, Seattle, WA 98109.	500138	08/24/2007	WA	Medical Imaging.
Alliance Imaging—The Vancouver Clinic, 700 NE 87th Avenue, Vancouver, WA 98664.	8864364	08/24/2007	WA	N/A.
Martin Center for Diagnostic and Imaging Services, 3901 S. Fremont Avenue, Springfield, MO 65804.	260040	08/24/2007	MO	N/A.
Aultman Hospital, 2600 Sixth Street SW, Canton, OH 44710	1457354318	08/24/2007	OH	N/A.
Imaging Consultants, Inc. at Harrington Memorial, 600 Federal Street, Andover, MA 01810.	327085	08/24/2007	MA	N/A.
Rhode Island Pet Services at Kent County, 600 Federal Street, Andover, MA 01810.	1538113113	08/24/2007	MA	N/A.
Imaging Consultants Inc. at Hawthorn, 600 Federal Street, Andover, MA 01810.	1851449078	08/24/2007	MA	N/A.

Facility name	Provider number	Date approved	State	Other information
Swedish Covenant Hospital, 5145 N California Avenue, Chicago, IL 60625.	362179813	08/24/2007	IL	N/A.
Banner Baywood Medical Center, 6644 E. Baywood Avenue, Mesa, AZ 85206.	30088	08/24/2007	AZ	N/A.
Lourdes Hospital, 1530 Lone Oak Road, Padukah, KY 42003 ...	1346244126	08/24/2007	KY	N/A.
St Vincent Oncology Center, 8301 Harcourt Road, Indianapolis, IN 46260.	150084	08/24/2007	IN	N/A.
United Hospital System, Inc., 9555 76th Street, Pleasant Prairie, WI 53518.	520021	08/24/2007	WI	N/A.
East Tennessee Diagnostic Center, 1450 Dowell Springs Boulevard, Suite 210, Knoxville, TN 37909.	1710932553	08/24/2007	TN	N/A.
Nazareth Hospital, 8400 Roosevelt Boulevard, Philadelphia, PA 19152.	390204A	08/24/2007	PA	N/A.
Good Samaritan Hospital, 2425 Samaritan Drive, San Jose, CA 95124.	50380	08/24/2007	CA	N/A.
MedSpecialists Imaging Center, 1064 Keene Road, Dunedin, FL 34698.	AB585	08/24/2007	FL	N/A.
NSMS—Pekin, IL, 2355 Broadway Road, Pekin, IL 61544	1295785079	08/24/2007	IL	N/A.
Bluegrass Regional Imaging, LLC, 701 Bob-O-Link Drive, Lexington, KY 40504.	1871542670	08/24/2007	KY	Suite 245.
Fairfax Pet Imaging Center, 8503 Arlington Boulevard, Fairfax, VA 22031.	1831220714	08/24/2007	VA	Suite 120LL.
Lodi Community Hospital, 225 Elyria Street, Lodi, OH 44254	361303	08/24/2007	OH	N/A.
Legacy Meridian Park Hospital, 19260 SW 65th Avenue, Suite 165, Tualatin, OR 97062.	380089	08/24/2007	OR	N/A.
Galion Community Hospital, 269 Portland Way South, Galion, OH 44833.	361325	08/24/2007	OH	N/A.
Oncology Hematology Associates of Central Illinois, 8940 N. Wood Sage Road, Peoria, IL 61615,.	616880	08/24/2007	IL	N/A.
Mid Ohio Oncology/Hematology, Inc., 3100 Plaza Properties Boulevard, Columbus, OH 43219.	1376509661	08/24/2007	OH	N/A.
Kentucky Imaging Center, 3475 Richmond Road, Lexington, KY 40509.	1992876981	08/24/2007	KY	SUITE 150.
Salem Community Hospital, 1995 East State Street, Salem, OH 44460.	1639131535	08/24/2007	OH	N/A.
Belmont Community Hospital, 51339 National Road, St. Clairsville, OH 43950.	360153	08/24/2007	OH	N/A.
Golder CT and MRI Center, 613 North Golder Avenue, Odessa, TX 79761.	N/A	08/24/2007	TX	N/A.
NSMS—Reedsburg, WI, 2000 North Dewey Street, Reedsburg, WI 53959.	1295785097	08/24/2007	WI	N/A.
MaineGeneral Medical Center, 361 Old Belgrade Road, Augusta, ME 04330.	200039A	08/24/2007	ME	N/A.
The Oklahoma PET Center, PLLC, 5401 N. Portland Avenue, Suite 330, Oklahoma City, OK 73112.	569959716M	08/24/2007	OK	N/A.
NSMS—Blytheville, AR, 1520 North Division Street, Blytheville, AR 72316.	1295785079	08/24/2007	AR	N/A.
NSMS—Benton, AR, 1 Medical Park Drive, Benton, AR 72015	1295785079	08/24/2007	AR	N/A.
Mercy Health System, 1000 Mineral Point Avenue, Janesville, WI 53548.	520066	08/24/2007	WI	N/A.
WA Foote Memorial Hospital, 205 N. East Avenue, Jackson, MI 49201.	230092	08/24/2007	MI	N/A.
Northern Michigan Hospital, 416 Connable Avenue, Petoskey, MI 49770.	230105	08/24/2007	MI	N/A.
Anchor Health Centers, 800 Goodlette Road N., Naples, FL 34102.	1174571608	08/24/2007	FL	Suite 130.
New Ulm Medical Center, 1324 5th North Street, New Ulm, MN 56073.	2880	08/24/2007	MN	N/A.
Radiology Associates of Brooklyn LLP, 2021 Avenue X, Brooklyn, NY 11235–2905.	1134244916	08/24/2007	NY	N/A.
NYOH Mobile PET/CT Hudson, 69 Prospect Road, Hudson, NY 12534.	1609863448	08/24/2007	NY	N/A.
Integris Bass Baptist Health Center, 600 South Monroe, Enid, OK 73703.	1144236571	08/24/2007	OK	N/A.
Imaging Consultants Inc at Weymouth Woods, 59 Performance Drive, Weymouth, MA 2188.	1487690335	08/24/2007	MA	N/A.
St. Vincent Medical Center, 2131 W. Third Street, Los Angeles, CA 90057.	50502	08/24/2007	CA	N/A.
Caritas PET Imaging, LLC at Holyoke Medical Center, 575 Beech Street, Holyoke, MA 1040.	327087	08/24/2007	MA	N/A.
St. James Healthcare, 400 South Clark, Butte, MT 59701	270017	08/24/2007	MT	N/A.
Inglewood Imaging Center, 211 N. Prairie Avenue, Inglewood, CA 90301.	TD097	08/24/2007	CA	N/A.

Facility name	Provider number	Date approved	State	Other information
Duncan Regional Hospital, 1700 Whisenant Drive, Duncan, OK 73534.	370023	08/24/2007	OK	PO Box 100.
OhioHealth Ambulatory PET/CT, 500 Thomas Lane, Columbus, OH 43214.	360006	08/24/2007	OH	N/A.
Baylor Diagnostic Imaging Center at Junius, 3900 Junius Street, Suite 100Dallas, TX 75246.	450021	08/24/2007	TX	N/A.
PET/CT Imaging at White Marsh, 9900 Franklin Square Drive, Suite D, Nottingham, MD 21236.	FMNX01	08/28/2007	MD	N/A.
Central Baptist Diagnostic Center, 100 Southland Drive, Lexington, KY 40503.	9375001	06/14/2006	KY	Suite B.
Baptist Health Medical Center—NLR PET/CT, 3500 Springhill Drive, North Little Rock, AR 72117.	5F437	05/03/2006	AR	Suite 100.
Commonwealth Hematology Oncology, 95 Bogle Office Park Drive, Somerset, KY 42503.	1285687178	03/21/2007	KY	N/A.
Commonwealth Hematology Oncology, 216 Southtown Drive, Danville, KY 40422.	1285687178	03/21/2007	KY	N/A.
Jefferson Center City Imaging, 850 Walnut Street, Philadelphia, PA 19107.	66277	09/07/2007	PA	N/A.
EPIC Imaging Center, 233 NE 102 Avenue, Portland, OR 97220.	0000WCGNQ	09/11/2007	OR	N/A.
UPMC and The Washington Hospital Cancer Center, 155 Wilson Avenue, Washington, PA 15301.	105589VXB	03/10/2006	PA	N/A.
Lexington Diagnostic Center, 1725 Harrodsburg Road, Suite 100, Lexington, KY 40504.	0406	03/08/2006	KY	N/A.
UW PET Imaging Center, 8007 Excelsior Drive, Madison, WI 53717.	1346266319	04/03/2007	WI	N/A.
NorCal Imaging—Oakland, 3200 Telegraph Avenue, Oakland, CA 94609.	ZZZ05319Z	08/22/2007	CA	N/A.
NorCal Imaging—Walnut Creek, 114 La Casa Via, Suite #100, Walnut Creek, CA 94598.	ZZZ05319Z	08/22/2007	CA	N/A.
Aurora Sheboygan Memorial Imaging Center, 2629 North 7th Street, Sheboygan, WI 53083.	520035	05/08/2008	WI.	
Aurora Memorial Hospital of Burlington, 252 McHenry Street, Burlington, WI 53105.	520059	05/08/2008	WI.	
Aurora Medical Center—Manitowoc County, 5000 Memorial Drive, Two Rivers, WI 54241.	520034	05/08/2008	WI.	

Addendum XIII—Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities [January Through March 2008]

On October 1, 2003, we issued our decision memorandum on ventricular assist devices for the clinical indication of destination therapy. We determined that ventricular assist devices used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for ventricular assist devices implanted as destination therapy.

The following facilities have met the CMS facility standards for destination therapy VADs.

VAD Destination Therapy Facilities

Facility	Provider No.	Date approved	State	Other information
Advocate Christ Medical Center, 4440 W 95th Street, Oak Lawn, Illinois ..	140208	12/17/2003	IL	
California Pacific Medical Center, 2333 Buchanan Street, San Francisco, California.	050047	03/19/2004	CA	
Baptist Memorial Hospital, 6019 Walnut Grove Road, Memphis, Tennessee.	440048	04/07/2004	TN	
Duke University Medical Center, DUMC Box 3943, Durham, North Carolina.	340030	10/31/2003	NC	
Fairview-University Medical Center, 2450 Riverside Avenue, Minneapolis, Minnesotta.	240080	10/28/2003	MN	
Allegheny General Hospital, 320 E North Avenue, Pittsburgh, Pennsylvania.	390050	12/10/2003	PA	
Barnes-Jewish Hospital, One Barnes-Jewish Hospital Plaza, Saint Louis, Missouri.	260032	10/27/2003	MO	
Brigham and Women's Hospital, 15 Francis Street, Boston, Massachusetts.	220110	01/09/2004	MA	
Bryan LGH Medical Center East, 1600 S 48 Street, Lincoln, Nebraska	280003	10/23/2003	NE	
Cedars-Sinai Medical Center, 8700 Beverly Boulevard, Los Angeles, California.	050625	12/29/2003	CA	
Clarian Health Partners, Inc., 1701 N. Senate Avenue, Indianapolis, Indiana.	150056	11/25/2003	IN	
Cleveland Clinic, 9500 Euclid Avenue, Cleveland, Ohio	360180	12/03/2003	OH	

VAD DESTINATION THERAPY FACILITIES—Continued

Facility	Provider No.	Date approved	State	Other information
Hahnemann University Hospital, Broad and Vine Streets, Philadelphia, Pennsylvania.	390290	12/22/2003	PA	
Hospital of the University of Pennsylvania, 3400 Spruce Street, Philadelphia, Pennsylvania.	390111	10/28/2003	PA	
Henry Ford Hospital, 2799 W. Grand Boulvard, Detroit, Michigan	230053	01/06/2004	MI	
Inova Fairfax Hospital, 3300 Gallows Road, Falls Church, Virginia	490063	03/31/2004	VA	
Jewish Hospital, 200 Abraham Flexner Way, Louisville, Kentucky	180040	11/10/2003	KY	
Jackson Memorial Hospital, 1611 NW 12th Avenue, Miami, Florida	100022	01/12/2004	FL	University of Miami.
LDS Hospital, 8th Avenue and C Street, Salt Lake City, Utah	460010	10/23/2003	UT	
Johns Hopkins Hospital, 600 N. Wolfe Street, Baltimore, Maryland	210009	10/28/2003	MD	
Loyola University Medical Center, 2160 S. 1st Avenue, Maywood, Illinois	140276	01/30/2004	IL	
Lutheran Hospital of Indiana, 7950 W. Jefferson Boulevard, Fort Wayne, Indiana.	150017	10/29/2003	IN	
Massachusetts General Hospital, 55 Fruit Street, Boston, Massachusetts	220071	12/15/2003	MA	
Mayo Clinic, 4500 San Pablo Road, Jacksonville, Florida	100151	11/06/2003	FL	
Medical City Dallas Hospital, 7777 Forest Lane, Dallas, Texas	450647	12/03/2003	TX	
The Methodist Hospital, 6565 Fannin Street, Houston, Texas	450358	11/03/2003	TX	
Montefiore Medical Center, 111 E. 210th Street, Bronx, New York	330059	11/14/2003	NY	
Methodist Specialty and Transplant Hospital, 8026 Floyd Curl Drive, San Antonio, Texas.	450388	11/19/2003	TX	
Newark Beth Israel Medical Center, 201 Lyons Avenue, Newark, New Jersey.	310002	11/14/2003	NJ	
Mount Sinai Medical Center, 1190 5th Avenue, New York, New York	330024	11/25/2003	NY	
New York-Presbyterian Hospital, 177 Fort Washington Avenue, New York, New York.	330101	10/28/2003	NY	Columbia University Medical Center.
Ohio State University Medical Center, 410 W. 10th Avenue, Columbus, Ohio.	360085	11/12/2003	OH	
Oregon Health and Sciences University, 3181 SW Sam Jackson Park Road, Portland, Oregon.	380009	11/21/2003	OR	
OSF St Francis Medical Center, 530 NE Glen Oak Avenue, Peoria, Illinois.	140067	11/12/2003	IL	
Penn State Milton S Hershey Medical Center, 500 University Drive, Hershey, Pennsylvania.	390256	10/29/2003	PA	
Rush-Presbyterian-St Luke Medical Center, 1653 W Congress Parkway, Chicago, Illinois.	140119	11/14/2003	IL	
Sentara Norfolk General Hospital, 600 Gresham Drive, Norfolk, Virginia ...	490007	11/10/2003	VA	
Sacred Heart Medical Center, 101 W 8th Avenue, Spokane, Washington	500054	01/12/2004	WA	
Seton Medical Center, 1201 W. 38th Street, Austin, Texas	450056	01/13/2004	TX	
Shands at the University of Florida, 1600 SW Archer Road, Gainesville, Florida.	100113	11/26/2003	FL	
Sharp Memorial Hospital, 7901 Frost Street, San Diego, California	050100	12/01/2003	CA	
Stanford University Hospital and Clinics, 300 Pasteur Drive, Stanford, California.	050441	12/22/2003	CA	Stanford University Medical Center.
St Francis Hospital, 6161 S. Yale Avenue, Tulsa, Oklahoma	370091	01/09/2004	OK	
St Luke's Medical Center, 2900 W Oklahoma Avenue, Milwaukee, Wisconsin.	520138	11/03/2003	WI	
St Luke's Episcopal Hospital, 6720 Bertner Avenue, Houston, Texas	450193	10/28/2003	TX	
St Vincent Hospital and Health Services, 2001 W. 86th Street, Indianapolis, Indiana.	150084	01/05/2004	IN	
St Paul Medical Center, 5909 Harry Hines Boulevard, Dallas, Texas	450044	12/10/2003	TX	
Strong Memorial Hospital, 601 Elmwood Avenue, Rochester, New York ...	330285	10/29/2003	NY	
Tampa General Hospital, 2 Columbia Drive, Tampa, Florida	100128	11/26/2003	FL	
Temple University Hospital, 3401 N. Broad Street, Philadelphia, Pennsylvania.	390027	11/03/2003	PA	
Tufts-New England Medical Center, 750 Washington Street, Boston, Massachusetts.	220116	11/06/2003	MA	
UCLA Medical Center, 10833 Le Conte Avenue, Los Angeles, California	050262	12/10/2003	CA	
University Medical Center, 1501 N. Campbell Avenue, Tucson, Arizonia ..	030064	10/29/2003	AZ	
University of Alabama at Birmingham Health System, 500 22nd Street S., Birmingham, Alabama.	010033	10/29/2003	AL	
University of Colorado Hospital, 4200 E. Ninth Avenue, Denver, Colorado	060024	11/06/2003	CO	9th & Colorado Campus.
The University of Chicago Hospitals and Health System, 5841 South Maryland Avenue, Chicago, Illinois.	140088	02/25/2004	IL	
University of Iowa Hospitals and Clinics, 200 Hawkins Drive, Iowa City, Iowa.	160058	11/12/2003	IA	
University of Maryland Medical Center, 22 S. Greene Street, Baltimore, Maryland.	210002	11/12/2003	MD	
University of Michigan Health System, 1500 E. Medical Center Drive, Ann Arbor, Michigan.	230046	10/27/2003	MI	
University of North Carolina Hospitals, 101 Manning Drive, Chapel Hill, North Carolina.	340061	05/05/2004	NC	
University of Utah Hospital, 50 N Medical Drive, Salt Lake City, Utah	460009	12/22/2003	UT	

VAD DESTINATION THERAPY FACILITIES—Continued

Facility	Provider No.	Date approved	State	Other information
University of Virginia Health System, 1215 Lee Street, Charlottesville, Virginia.	490009	01/12/2004	VA	
University of Washington Medical Center, 1959 NE Pacific Street, Seattle, Washington.	500008	01/15/2004	WA	
University of Wisconsin Hospitals and Clinics, 600 Highland Avenue, Madison, Wisconsin.	520098	12/03/2003	WI	
USC University Hospital, 1500 San Pablo, Los Angeles, California	050696	01/09/2004	CA	
UPMC Presbyterian, 200 Lothrop Street, Pittsburgh, Pennsylvania	390164	10/23/2003	PA	
Virginia Commonwealth University Medical Center, 401 North 12th Street, Richmond, Virginia.	490032	04/08/2004	VA	Medical College of Virginia Hospitals.
Vanderbilt University Medical Center, 1161 21st Avenue S., Nashville, Tennessee.	440039	10/28/2003	TN	
Ochsner Clinic Foundation, 1514 Jefferson Highway, New Orleans, Louisiana.	190036	06/29/2004	LA	
Baylor University Medical Center, 3500 Gaston Avenue, Dallas, TX 75246	N/A	10/04/2007	TX	
The University of Michigan Hospitals and Health Centers, 1500 East Medical Center Drive, Ann Arbor, MI 48109.	230046	03/28/2008	MI	
Saint Mary's Hospital, 1216 Southwest Second Street, Rochester, MN 55902.	N/A	02/27/2008	MN	
Allegheny General Hospital, 320 East North Avenue, Pittsburgh, PA 15212.	N/A	03/08/2008	PA	
Washington Hospital Center, 110 Irving Street, NW., Washington, DC 20010.	09-0011	04/23/2008	DC	

Addendum XIV—Lung Volume Reduction Surgery (LVRS) [January Through March 2008]

Three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS): National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs), Credentialed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) under their Disease Specific Certification Program for LVRS, and Medicare approved for lung transplants. Only the first two types are in the list.

Facility name	Date approved	State	Type of certification
Baylor College of Medicine, Houston, Texas	N/A	TEXAS	NETT.
Brigham and Women's Hospital, Boston, MA	N/A	MASSACHUSETTS	NETT.
Cedars-Sinai Medical Center, Los Angeles, CA	N/A	CALIFORNIA	NETT.
Chapman Medical Center, Orange, CA	N/A	CALIFORNIA	NETT.
Cleveland Clinic Foundation, Cleveland, OH	N/A	OHIO	NETT.
Columbia University, New York, NY	N/A	NEW YORK	NETT.
Duke University Medical Center, Durham, NC	N/A	NORTH CAROLINA	NETT.
Johns Hopkins Hospital, Baltimore, MD	N/A	MARYLAND	NETT.
Kaiser Foundation Hospital—Riverside, Riverside, CA	09/20/2006	CALIFORNIA	JCAHO.
Long Island Jewish Medical Center, New Hyde Park, NY	N/A	NEW YORK	NETT.
Mayo Clinic, Rochester, MN	N/A	MINNESOTA	NETT.
Memorial Medical Center, Springfield, IL	12/13/2006	ILLINOIS	JCAHO.
National Jewish Medical Center, Denver, CO	N/A	COLORADO	NETT.
The Ohio State University Hospital, Columbus, OH	N/A	OHIO	JCAHO.
Ohio State University Medical Center, Columbus, OH	N/A	OHIO	NETT.
Saint Louis University, Saint Louis, MO	N/A	MISSOURI	NETT.
Temple University Hospital, Philadelphia, PA	N/A	PENNSYLVANIA	NETT.
UCLA Medical Center, Los Angeles, CA	N/A	CALIFORNIA	NETT.
University of California, San Diego, San Diego, CA	N/A	CALIFORNIA	NETT.
University of Maryland Medical Center, Baltimore, MD	N/A	MARYLAND	NETT.
University of Michigan Medical Center, Ann Arbor, MI	N/A	MICHIGAN	NETT.
University of Pennsylvania, Philadelphia, PA	N/A	PENNSYLVANIA	NETT.
University of Pittsburgh, Pittsburgh, PA	N/A	PENNSYLVANIA	NETT.
University of Washington, Seattle, WA	N/A	WASHINGTON	NETT.
Washington University/Barnes Hospital, Saint Louis, MO	N/A	MISSOURI	NETT.

Addendum XV—Medicare-Approved Bariatric Surgery Facilities

On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) Certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and

requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

The following facilities have met our minimum facility standards for bariatric surgery and have been certified by American College of Surgeons (ACS) or American Society for Metabolic and Bariatric Surgery (ASMBS).

Facility name	Provider No.	Date approved	State	Other information
Evanston Northwestern Hospital, 2650 Ridge Avenue, Suite 1308, Evanston, IL 60201.	140010	01/26/2006	IL	ACS.
Chapman Medical Center, 2601 East Chapman Avenue, Orange, CA 92646.	05–0745	02/21/2006	CA ...	ASMBS.
St Vincent Carmel Hospital, 13430 Old Meridian Street, Suite 168, Carmel, IN 46032.	15–0157	02/21/2006	IN	ASMBS.
Abbott Northwestern Hospital, 800 E. 28th Street, Minneapolis, MN 55407.	N/A	02/24/2006	MN ..	ASMBS.
Alexian Brothers Medical Center, 800 Biesterfield Road, Elk Grove Village, IL 60007.	N/A	02/24/2006	IL	ASMBS.
American Bariatric Institute at Doctors' Hospital, 1130 Louisiana Avenue, Shreveport, LA 71101.	N/A	02/24/2006	LA ...	ASMBS.
Arnot Ogden Medical Center, 600 Fitch Street, Elmira, NY 14905.	330090	02/24/2006	NY ...	ASMBS.
AtlantiCare Regional Medical Center, 2500 English Creek Avenue, Egg Harbor Township, NJ 08234.	N/A	02/24/2006	NJ ...	Center for Surgical Weight Loss and Wellness Salartash Surgical Associates ASMBS.
Atlanta Medical Center, 303 Parkway Drive NE, Atlanta, GA 30312.	N/A	02/24/2006	GA ..	ASMBS.
Aurora Sinai Medical Center, 945 N. 12th Street, Milwaukee, WI 53211.	N/A	02/24/2006	WI ...	ASMBS.
Baptist Memorial Hospital—North Mississippi, 2301 South Lamar Boulevard, Oxford, MS 38655.	N/A	02/24/2006	MS ..	ASMBS.
Bellin Health, 215 N. Webster Avenue, Green Bay, WI 54301.	N/A	02/24/2006	WI ...	ASMBS.
Bon Secours Community Hospital, 160 E. Main Street, Port Jervis, NY 12771.	N/A	02/24/2006	NY ...	ASMBS.
California Pacific Medical Center, 2333 Buchanan Street, San Francisco, CA 94115.	N/A	02/24/2006	CA ...	ASMBS.
Cape Fear Valley Health System, 1638 Owen Drive, Fayetteville, NC 28304.	N/A	02/24/2006	NC ..	ASMBS.
Centennial Center for the Treatment of Obesity, 2300 Patterson Street, Nashville, TN 37203.	N/A	02/24/2006	TN ...	ASMBS.
Cleveland Clinic Hospital-Weston, 3100 Weston Road, Weston, FL 33331.	N/A	02/24/2006	FL ...	ASMBS.
Christus Schumpert Health System, 1 Saint Mary Place, Shreveport, LA 71101.	N/A	02/24/2006	LA ...	ASMBS.
Citizen's Bariatric Center, 2701 Hospital Avenue, Victoria, TX 77901.	N/A	02/24/2006	TX ...	ASMBS.
Columbia-St. Mary's Bariatric Center, 2025 E. Newport Avenue, Milwaukee, WI 53211.	N/A	02/24/2006	WI ...	ASMBS.
Community Hospital Monterey Peninsula, 23625 Holman Highway, Monterey, CA 93940.	N/A	02/24/2006	CA ...	ASMBS.
Crestwood Medical Center, One Hospital Drive, Huntsville, AL 35801.	N/A	02/24/2006	AL ...	ASMBS.
Cypress Fairbanks Medical Center Hospital, 10655 Steepletop Drive, Houston, TX 77065.	450716	02/24/2006	TX ...	ASMBS.
Danbury Hospital, 24 Hospital Avenue, Danbury, CT 06810.	N/A	02/24/2006	CT ...	ACS.
East Texas Medical Center, 1000 S. Beckman Avenue, Tyler, TX 75701.	N/A	02/24/2006	TX ...	ASMBS.
Eastern Maine Medical Center, 905 Union Street, EMH Mall, Suite 11, Bangor, ME 04401.	200033	02/24/2006	ME ..	ASMBS.
Elmbrook Memorial Hospital, 19333 W. North Avenue, Brookfield, WI 53045.	N/A	02/24/2006	WI ...	ASMBS.
Emory Dunwoody Medical Center, 4575 N. Shallowford Road, Atlanta, GA 30338.	N/A	02/24/2006	GA ..	ASMBS.
Florida Hospital Celebration Health, 400 Celebration Place, Kissimmee, FL 34747.	N/A	02/24/2006	FL ...	ASMBS.
Florida Medical Center, 4850 W. Oakland Boulevard, Lauderdale Lakes, FL 33313.	N/A	02/24/2006	FL ...	ASMBS.
Froedtert Memorial Lutheran Hospital, 9200 W. Wisconsin Avenue, Milwaukee, WI 53226.	N/A	02/24/2006	WI ...	Medical College of Wisconsin ASMBS.
Frye Regional Medical Center, 420 N. Center Street, Hickory, NC 28601.	N/A	02/24/2006	NC ..	ASMBS.
Geisinger Medical Center, 100 North Academy Avenue, Danville, PA 17822.	390006	N/A	PA ...	ASMBS–02/24/2006 ACS–01/26/2007.

Facility name	Provider No.	Date approved	State	Other information
Good Samaritan Hospital, 375 Dixmyth Avenue, Cincinnati, OH 45220.	N/A	02/24/2006	OH ..	ASMBS.
Grandview Medical Center, 405 Grand Avenue, Dayton, OH 45405.	N/A	02/24/2006	OH ..	ASMBS.
Greater Baltimore Medical Center, 6701 N. Charles Street, Baltimore, MD 21204.	N/A	02/24/2006	MD ..	ASMBS.
Hamilton Medical Center, 1200 Memorial Drive, Dalton, GA 30720.	N/A	02/24/2006	GA ..	ASMBS.
Hennepin County Medical Center, 701 Park Avenue, Minneapolis, MN 55415.	N/A	02/24/2006	MN ..	ASMBS.
Holy Cross Hospital, 4725 N. Federal Highway, Fort Lauderdale, FL 33308.	N/A	02/24/2006	FL ...	ASMBS.
Hospital of Saint Raphael, 1450 Chapel Street, New Haven, CT 06511.	N/A	02/24/2006	CT ...	ASMBS.
Huntington Memorial Hospital, 100 W. California Boulevard, Pasadena, CA 91105.	N/A	02/24/2006	CA ...	ASMBS.
Jupiter Medical Center, 1210 S. Old Dixie Highway, Jupiter, FL 33458.	N/A	02/24/2006	FL ...	ASMBS.
King's Daughters Medical Center, 617 23rd Street, Ashland, KY 41101.	N/A	02/24/2006	KY ...	ASMBS.
Legacy Good Samaritan Hospital and Medical Center, 1015 NW 22nd Avenue, Portland, OR 97210.	N/A	02/24/2006	OR ..	ASMBS.
Lexington Medical Center, 2720 Sunset Boulevard, West Columbia, SC 29169.	N/A	02/24/2006	SC ...	ASMBS.
Little Company of Mary, 2800 W. 95th Street, Evergreen Park, IL 60805.	N/A	02/24/2006	IL	ASMBS.
Lutheran Medical Center, 150 55th Street, Brooklyn, NY 11220.	29D361	02/24/2006	NY ...	ACS.
Medical University of South Carolina, 171 Ashley Avenue, Charleston, SC 29425.	N/A	02/24/2006	SC ...	ASMBS.
Memorial Hermann Hospital, 6411 Fannin Street, Houston, TX 77030.	N/A	02/24/2006	TX ...	ASMBS.
Memorial Hospital, 2525 DeSales Avenue, Chattanooga, TN 37404.	N/A	02/24/2006	TN ...	ASMBS.
Mercy Hospital Miami, 3663 South Miami Avenue, Miami, FL 33133.	N/A	02/24/2006	FL ...	ASMBS.
Mercy San Juan Medical Center, 6501 Coyle Avenue, Carmichael, CA 95608.	N/A	02/24/2006	CA ...	ASMBS.
Metabolic Surgery Center at Baptist Hospital, 2011 Church Street, Nashville, TN 37203.	N/A	02/24/2006	TN ...	ASMBS.
Methodist Dallas Medical Center, PO Box 655999, Dallas, TX 75265–5999.	N/A	02/24/2006	TX ...	Texas Bariatric Center ASMBS.
Methodist Healthcare System, 8109 Fredricksburg Road, San Antonio, TX 78229.	N/A	02/24/2006	TX ...	ASMBS.
Methodist Hospital, 6500 Excelsior Boulevard, Saint Louis Park, MN 55426.	N/A	02/24/2006	MN ..	ASMBS.
Middlesex Hospital, 28 Crescent Street, Middletown, CT 06457.	N/A	02/24/2006	CT ...	ASMBS.
Methodist Hospital of Southern California, 300 West Huntington Drive, Arcadia, CA 91007.	N/A	02/24/2006	CA ...	ASMBS.
Mills-Peninsula Health Services, 1783 El Camino Real, Burlingame, CA 94010.	N/A	02/24/2006	CA ...	ASMBS.
New Hanover Regional Medical Center, 2131 S. 17th Street, Wilmington, NC 28401.	N/A	02/24/2006	NC ..	ASMBS.
New York Methodist Hospital, 506 Sixth Street, Brooklyn, NY 11215.	N/A	02/24/2006	NY ...	ASMBS.
North Hills Hospital, 4401 Booth Calloway Road, North Richland Hills, TX 76180.	N/A	02/24/2006	TX ...	ASMBS.
North Colorado Medical Center, 1801 16th Street, Greeley, CO 80631.	N/A	02/24/2006	CO ..	ASMBS.
North Vista Hospital, 1409 E. Lake Mead Boulevard, North Las Vegas, NV 89101.	N/A	02/24/2006	NV ...	ASMBS.
Northeast Georgia Health System, Inc., 743 Spring Street, NE, Gainesville, GA 30501.	N/A	02/24/2006	GA ..	ASMBS.
NorthEast Medical Center, 920 Church Street N., #302E, Concord, NC 28025.	N/A	02/24/2006	NC ..	ASMBS.
Northwestern Memorial Hospital, 215 E. Huron Street, NE, Chicago, IL 60611.	N/A	02/24/2006	IL	Northwestern Medical Faculty Foundation ASMBS.
Ocala Regional Medical Center, 1431 SW 1st Street, Ocala, FL 34474.	N/A	02/24/2006	FL ...	ASMBS.
Palms of Pasadena Hospital, 1501 Pasedena Avenue, St. Petersburg, FL 33707.	N/A	02/24/2006	FL ...	ASMBS.
Orange Coast Memorial Medical Center, 9920 Talbert Avenue, Fountain Valley, CA 92708.	N/A	02/24/2006	CA ...	ASMBS.

Facility name	Provider No.	Date approved	State	Other information
Parkwest Medical Center, 9352 Park West Boulevard, Knoxville, TN 37923.	N/A	02/24/2006	TN ...	ASMBS.
Penrose-St. Francis Health Services, 825 E. Pikes Peak Avenue, Colorado Springs, CO 80917.	N/A	02/24/2006	CO ..	ASMBS.
Poudre Valley Hospital, 1024 S. Lemay Avenue, Fort Collins, CO 80524.	N/A	02/24/2006	CO ..	ASMBS.
Presbyterian-St. Luke's Medical Center, 1719 E. 19th Avenue, Denver, CO 80218.	N/A	02/24/2006	CO ..	ASMBS.
Princeton HealthCare System, 253 Witherspoon Street, Princeton, NJ 08540.	N/A	02/24/2006	NJ ...	ASMBS.
Roger Williams Medical Center, 825 Chalkstone Avenue, Providence, RI 02908.	N/A	02/24/2006	RI	Drs. Lentrichia & Pohl, Inc. ASMBS.
Rose Medical Center, 4545 E. 9th Avenue, #470, Denver, CO 80220.	N/A	02/24/2006	CO ..	ASMBS.
Saint Barnabas Medical Center, 94 Old Short Hills Road, Livingston, NJ 07039.	N/A	02/24/2006	NJ ...	ASMBS.
Saint Francis Hospital, 5959 Park Avenue, Memphis, TN 38119.	N/A	02/24/2006	TN ...	ASMBS.
St. Francis Hospital-Franciscan Health System, 34515 Ninth Avenue S., Federal Way, WA 98003.	N/A	02/24/2006	WA ..	N/A.
Saint Joseph East Center for Weight Loss, 160 N. Eagle Creek Drive, Lexington, KY 40509.	N/A	02/24/2006	KY ...	ASMBS.
Saint Mary's Regional Medical Center, 234 W. 6th Street, Reno, NV 89503.	N/A	02/24/2006	NV ...	ASMBS.
Saint Mary's Hospital, 5801 Bremo Road, Richmond, VA 23226.	N/A	02/24/2006	VA ...	ASMBS.
Scottsdale Healthcare Shea Campus, 900 E. Shea Boulevard, Scottsdale, AZ 85260.	N/A	02/24/2006	AZ ...	ASMBS.
Scripps Memorial, 9888 Genesee Avenue, La Jolla, CA 90237.	N/A	02/24/2006	CA ...	ASMBS.
Scripps Mercy Hospital, 4077 Fifth Avenue, San Diego, CA 92103.	N/A	02/24/2006	CA ...	ASMBS.
Sentara Careplex Hospital, 3000 Coliseum Drive, Hampton, VA 23666.	N/A	02/24/2006	VA ...	ASMBS.
Sinai Hospital of Baltimore, 2401 W. Belvedere Avenue, Baltimore, MD 21215.	N/A	02/24/2006	MD ..	Sinai Surgical Associates ASMBS.
Sisters of Charity Hospital, 2130 Main Street, Buffalo, NY 14214.	N/A	02/24/2006	NY ...	ASMBS.
Sioux Valley Hospital USD Medical Center, 1305 W. 18th Street, Sioux Falls, SD 57105.	N/A	02/24/2006	SD ...	ASMBS.
Sound Shore Medical Center of Westchester, 16 Guion Place, New Rochelle, NY 10801.	N/A	02/24/2006	NY ...	ASMBS.
South Nassau Communities Hospital, 1 Healthy Way, Oceanside, NY 11572.	N/A	02/24/2006	NY ...	ASMBS.
Southwest Healthcare System, 36485 Inland Valley Drive, Wildomar, CA 92595.	N/A	02/24/2006	CA ...	ASMBS.
Southwest Medical Center, 2810 Ambassador Caffery Parkway, Lafayette, LA 70506.	N/A	02/24/2006	LA ...	ASMBS.
Spectrum Health Blodgett Campus, 1840 Wealthy Street, SE, Grand Rapids, MI 49506.	N/A	02/24/2006	MI	MMPC Center for Health Excellence ASMBS.
SSM DePaul Health Center, 12303 DePaul Avenue, Bridgeton, MO 63044.	N/A	02/24/2006	MO ..	ASMBS.
St. Joseph's Area Health Services, 600 Pleasant Avenue, Park Rapids, MN 56470.	N/A	02/24/2006	MN ..	ASMBS.
St. Vincent Charity Hospital, 2322 E. 22nd Street, #220, Cleveland, OH 44115.	N/A	02/24/2006	OH ..	ASMBS.
Staten Island University Hospital, 475 Seaview Avenue, Staten Island, NY 10305.	N/A	02/24/2006	NY ...	ASMBS.
Theda Clark Medical Center, 200 Theda Clark Medical Plaza, Suite 410, Neenah, WI 54956.	000071445	02/24/2006	WI ...	ACS.
The Ohio State University Hospital, 410 W. 10th Avenue, Columbus, OH 43210.	N/A	02/24/2006	OH ..	ASMBS.
The Regional Medical Center at Memphis, 877 Jefferson Avenue, Memphis, TN 38103.	N/A	02/24/2006	TN ...	ASMBS.
Tri-City Regional Medical Center, 21530 Pioneer Boulevard, Hawaiian Gardens, CA 90716.	N/A	02/24/2006	CA ...	ASMBS.
United Hospital, 333 North Smith Avenue, Saint Paul, MN 55102.	N/A	02/24/2006	MN ..	ASMBS.
United Regional Health Care System, 1600 19th Street, Wichita Falls, TX 76301.	N/A	02/24/2006	TX ...	ASMBS.
Unity Hospital, 550 Osborne Road, NE, Fridley, MN 55432.	N/A	02/24/2006	MN ..	ASMBS.
University of Chicago Hospitals, 5841 S. Maryland Avenue, Chicago, IL 60637.	N/A	02/24/2006	IL	University of Chicago Department of Surgery ASMBS.

Facility name	Provider No.	Date approved	State	Other information
University of Minnesota Medical Center, Fairview, 2450 Riverside Avenue, Minneapolis, MN 55454.	24–0080	02/24/2006	MN ..	ASMBS.
UPMC St. Margaret, 815 Freeport Road, Pittsburgh, PA 15215.	N/A	02/24/2006	PA ...	ASMBS.
UPMC Horizon, 110 North Main Street, Greenville, PA 16125.	N/A	02/24/2006	PA ...	ASMBS.
Virginia Commonwealth University Medical Center Richmond, VA 23284.	N/A	02/24/2006	VA ...	ASMBS.
Vanderbilt University Medical Center, 1211 22nd Avenue S., Nashville, TN 37232.	N/A	02/24/2006	TN ...	ASMBS.
Weight Loss Surgery Program at Baylor, 9101 N. Central Expressway, Suite 370, Dallas, TX 75231.	N/A	02/24/2006	TX ...	ASMBS.
Wellstar Health Systems, 677 Church Street, NE, Marietta, GA 30060.	N/A	02/24/2006	GA ..	ASMBS.
White Plains Hospital Center, 190 E. Post Road, White Plains, NY 10601.	N/A	02/24/2006	NY ...	ASMBSs
York Hospital, 1001 S. George Street, York, PA 17403 ...	N/A	02/24/2006	PA ...	ASMBS.
Norman Regional Hospital, 901 North Porter, Box 1308, Norman, OK 73070.	370008	03/22/2006	OK ..	ASMBS.
St. Luke's Medical Center, 1800 E. Van Buren, Suite 307B, Phoenix, AZ 85006.	030037	03/22/2006	AZ ...	Abdominal Surgeons, Ltd. ASMBS.
Silver Cross Hospital, 1200 Maple Road, Joliet, IL 60432	140213	03/22/2006	IL	Midwest Comprehensive Bariatrics ASMBS.
Tampa General Hospital, 2 Columbia Drive, F145, Tampa, FL 33601.	100128	03/22/2006	FL ...	University of South Florida ASMBS.
Spartanburg Regional Healthcare System, 101 East Wood Street, Spartanburg, SC 29303.	420007	03/27/2006	SC ...	ASMBS.
OSF Saint Francis Medical Center, 530 NE Glen Oak Avenue, Peoria, IL 61637.	140067	04/05/2006	IL	ASMBS.
Palmetto Health Baptist, 1850 Laurel Street, Suite 1A, Columbia, SC 29201.	420086	04/05/2006	SC ...	ASMBS.
Peconic Bay Medical Center, 1300 Roanoke Avenue, Riverhead, NY 11901.	330107	04/06/2006	NY ...	ASMBS.
Desert Springs Hospital, 2075 East Flamingo, Las Vegas, NV 89119.	290022	04/07/2006	NV ...	ASMBS.
Palmetto General Hospital, 2001 West 68th Street, Hialeah, FL 33016.	100187	04/11/2006	FL ...	ASMBS.
Hurley Medical Center, One Hurley Plaza, Flint, MI 48503–5993.	230132	04/14/2006	MI	ACS.
University of California, Davis, 2315 Stockton Boulevard, Sacramento, CA 95817.	N/A	04/18/2006	CA ...	ASMBS.
Russell County Medical, Carroll and Tate Streets, Lebanon, VA 24266.	N/A	04/27/2006	VA ...	ASMBS.
Western Pennsylvania Hospital, 4800 Friendship Avenue, Pittsburgh, PA 15224.	028672	N/A	PA ...	ASMBS–05/01/2006 ACS–10/16/2006.
Banner Good Samaritan Bariatric Center, 1300 North 12th Street, Suite 610, Phoenix, AZ 85006.	N/A	05/04/2006	AZ ...	ASMBS.
Bothwell Regional Health Center, 601 East 14th Street, Sedalia, MO 65301.	N/A	05/17/2006	MO ..	ASMBS.
Durham Regional Hospital, 3643 N. Roxboro Road, Durham, NC 27704.	N/A	05/17/2006	NC ..	ASMBS.
Fairview Southdale Hospital, 6405 France Avenue Street, Suite W320 Edina, MN 55435.	N/A	05/17/2006	MN ..	ASMBS.
Cleveland Clinic, 9500 Euclid Avenue (A80), Cleveland, OH 44195.	360180	N/A	OH ..	05/24/2006–ASMBS 12/01/2006–ACS.
St. Agnes Healthcare, 900 Caton Avenue, Baltimore, MD 21229.	210011	05/24/2006	MD ..	ASMBS.
Sycamore Hospital, 2150 Leiter Road, Miamisburg, OH 45342.	360239	05/24/2006	OH ..	ASMBS.
Albany Medical Center, 47 New Scotland Avenue, Albany, NY 12208.	330013	06/02/2006	NY ...	ACS.
Georgetown Community Hospital, 1140 Lexington Road, Georgetown, KY 40324.	180101	06/07/2006	KY ...	ASMBS.
Fletcher Allen Health Care, 111 Colchester Avenue, Burlington, VT 05401.	N/A	06/09/2006	VT ...	Hospital: 470003 Group Provider: VN0997 ACS.
New York-Presbyterian Hospital/Columbia University Medical Center, 622 W. 168th Street, New York, NY 10032.	330101	06/14/2006	NY ...	ACS.
Providence Memorial Hospital, 2001 North Oregon Street, El Paso, TX 79902.	450668	06/15/2006	TX ...	ASMBS.
UT Southwestern University Hospitals-Zale Lipshy, 5909 Harry Hines Boulevard, Dallas, TX 75390.	450766	06/19/2006	TX ...	ASMBS.
Cedars-Sinai Medical Center, 8700 Beverly Boulevard, Los Angeles, CA 90048.	N/A	06/20/2006	CA ...	Thalians—2W ACS.

Facility name	Provider No.	Date approved	State	Other information
Community Medical Center-Clovis, 2755 Herndon Avenue, Clovis, CA 93611.	050492	N/A	CA ...	ACS–06/26/2006 ASMBS–12/07/2006.
Oregon Health & Science University, 3181 SW Sam Jackson Park Road, L223A, Portland, OR 97239.	See other information	06/27/2006	OR ..	OHSU Medical Group—107708 OHSU Hospital—380009 ACS.
Hospital of the University of Pennsylvania, 3400 Spruce Street, 4 Silverstein, Philadelphia, PA 19104.	N/A	07/06/2006	PA ...	ASMBS.
Swedish Medical Center, 501 East Hampden Avenue, Englewood, CO 80113.	060034	07/06/2006	CO ..	ASMBS.
Blount Memorial Hospital, 907 East Lamar Alexander Parkway, Maryville, TN 37801.	440011	07/11/2006	TN ...	ASMBS.
University of Virginia Health System, PO Box 800809, Charlottesville, VA 22908–0809.	490009	07/12/2006	VA ...	ACS.
Sewickley Valley Hospital, 720 Blackburn Road, Sewickley, PA 15143.	390037	07/13/2006	PA ...	ASMBS.
The Christ Hospital, 2139 Auburn Avenue, Cincinnati, OH 45219.	360163	07/17/2006	OH ..	ASMBS.
Cabell Huntington Hospital, 1340 Hal Greer Boulevard, Huntington, WV 25701.	510055	07/19/2006	WV ..	ASMBS.
Mount Sinai Hospital, One Gustave L. Levy Place, 1190 5th Avenue, New York, NY 10029.	330024	07/25/2006	NY ...	ASMBS.
UMass Memorial Medical Center—Memorial Campus, 119 Belmont Street, Worcester, MA 01605.	A22819	07/27/2006	MA ..	ACS.
Henry Ford Hospital, 2799 West Grand Boulevard, Detroit, MI 48202.	N/A	07/31/2006	MI	ASMMBS.
Vista Surgical Hospital, 9094 Perkins Road, Suite B, Baton Rouge, LA 70810.	230053	07/31/2006	LA ...	ASMBS.
Town & Country Hospital, 6001 Webb Road, Tampa, FL 33615.	100255	08/02/2006	FL ...	ASMBS.
New York-Presbyterian Hospital/Weill Cornell Medical Center, 630 West 168th Street, New York, NY 10032.	330101	08/04/2006	NY ...	ACS.
Centinela Freeman Regional Medical Center, 4650 Lincoln Boulevard, Marin del Rey, CA 90292.	050741	08/07/2006	CA ...	ASMBS.
NYU Medical Center, 560 First Avenue, New York, NY 10016.	330214	08/08/2006	NY ...	ASMBS.
Regional West Medical Center, 4021 Avenue B, Scottsbluff, NE 69361.	280061	08/08/2006	NE ...	ASMBS.
Mercy Medical Center, 1000 North Village Avenue, Rockville Centre, NY 11570.	N/A	08/10/2006	NY ...	ASMBS.
Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115–6195.	M20830	08/14/2006	MA ..	ACS.
Highland Hospital, 1000 South Avenue, Rochester, NY 14620.	330164	08/30/2006	NY ...	ACS.
Inova Fair Oaks Hospital, 3600 Joseph Siewick Drive, Fairfax, VA 22033.	490101	08/31/2006	VA ...	ASMBS.
Our Lady of Lourdes Medical Center, 1600 Haddon Avenue, Camden, NJ 08104.	613039	08/31/2006	NJ ...	ASMBS.
FirstHealth Moore Regional Hospital, 155 Memorial Drive, Pinehurst, NC 27374.	340115	09/01/2006	NC ..	ASMBS.
Hamot Medical Center, 201 State Street, Erie, PA 16550	390063	09/01/2006	PA ...	ASMBS
St. Alexius Hospital-NewStart, 3933 South Broadway Street, St. Louis, MO 63118.	260210	09/01/2006	MO ..	ASMBS.
St. Catherine of Siena Medical Center, 50 Route 25A, Smithtown, NY 11787.	316495	09/01/2006	NY ...	ASMBS.
Barnes Jewish Hospital, One Barnes-Jewish Hospital Plaza, St. Louis, MO 63110.	260032	09/06/2006	MO ..	ASMBS.
Baptist Memorial Hospital Memphis, 6025 Walnut Grove Road, Memphis, TN 38120.	440048	09/07/2006	TN ...	ASMBS.
Norwalk Hospital, 24 Stevens Street, Norwalk, CT 06856	070034	09/07/2006	CT ...	ASMBS.
North Shore University Hospital at Manhasset, 300 Community Drive, Manhasset, NY 11530.	330106	09/08/2006	NY ...	ASMBS.
St. Vincent's Medical Center, 2800 Main Street, Bridgeport, CT 06606.	070028	09/08/2006	CT ...	Level 3-Department of Surgery, ASMBS.
Faxton-St. Luke's Healthcare, 1656 Champlin Avenue, Utica, NY 13503.	330044	09/14/2006	NY ...	ASMBS.
St. Joseph's Hospital, 69 West Exchange, St. Paul, MN 55102.	N/A	09/14/2006	MN ..	ASMBS.
Johns Hopkins Bayview Medical Center, 4940 Eastern Avenue, Baltimore, MD 21224.	210029	09/15/2006	MD ..	ASMBS.
University Hospitals of Cleveland, 11100 Euclid Avenue, Cleveland, OH 44106.	N/A	09/15/2006	OH ..	ASMBS.
Yale-New Haven Hospital, 20 York Street, New Haven, CT 06510.	070022	09/20/2006	CT ...	ASMBS.
Avera McKennan Hospital, 800 East 21st Street, Box 5045, Sioux Falls, SD 57117–5045.	430016	09/25/2006	SD ...	ASMBS.

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Memorial Hospital Jacksonville, 3625 University Boulevard South, Jacksonville, FL 32216.	100179	09/26/2006	FL ...	ASMBS.
Fountain Valley Regional Hospital, 17100 Euclid Street, Fountain Valley, CA 92708.	050570	09/27/2006	CA ...	ASMBS.
Sentara Norfolk General Hospital, 600 Gresham Drive, Norfolk, VA 23507.	4900073	09/29/2006	VA ...	ACS.
St. Mary's Medical Center, 450 Stanyan Street, San Francisco, CA 94117.	050457	10/02/2006	CA ...	ASMBS.
Trinity Medical Center, 800 Montclair Road, Birmingham, AL 35213.	010104	10/03/2006	AL ...	ASMBS.
MeritCare Health System, 720 4th Street North, Fargo, ND 58122.	350011	10/11/2006	ND ..	ASMBS.
St. Lukes's/Roosevelt, 1090 Amsterdam Avenue, New York, NY 10025.	330046	10/11/2006	NY ...	10th Floor, ACS.
Benefis Healthcare, 1101 26th Street South, Great Falls, MT 59405.	270012	10/13/2006	MT ..	ASMBS.
Mason General Hospital, 901 Mountain View Drive, Shelton, WA 98584.	501336	10/13/2006	WA ..	ASMBS.
Norton Hospital, 200 East Chestnut, Louisville, KY 40202	180088	10/16/2006	KY ...	ASMBS.
Port Huron Hospital, 1221 Pine Grove Avenue, Port Huron, MI 48060.	230216	10/16/2006	MI	ASMBS.
Harper University Hospital, 3990 John R. Street, Detroit, MI 48201.	230104	10/17/2006	MI	ASMBS.
St. Luke Hospital, 7380 Turfway Road, Florence, KY 41042.	180045	10/18/2006	KY ...	ASMBS.
Twelve Oaks Medical Center Hospital, 4200 Twelve Oaks Drive, Houston, TX 77027.	N/A	10/18/2006	TX ...	ASMBS.
Cleveland Clinic Florida, 3100 Weston Road, Weston, FL 33331–3602.	100289	10/19/2006	FL ...	ACS.
Grinnell Regional Medical Center, 210 Fourth Avenue, Grinnell, IA 50112.	N/A	10/19/2006	IA	Provider Numbers: Hospital: 160147, Surgical Group: 03108, ACS.
Conway Medical Services, 300 Singleton Ridge Road, Conway, SC 29528.	420049	10/20/2006	SC ...	ASMBS.
Alta Bates Medical Center, 350 Hawthorne Avenue, Oakland, CA 94609.	050043	10/23/2006	CA ...	ASMBS.
Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114–2696.	220071	10/23/2006	MA ..	ACS.
Mayo Clinic-Saint Mary's Hospital, 200 First Street, SW, Rochester, MN 55905.	N/A	10/23/2006	MN ..	SMH: 24–0010, Part B General Medical: C01384, ACS.
Saint Francis Hospital, 6465 South Yale Avenue, #900, Tulsa, OK 74136.	372308	10/23/2006	OK ..	ACS.
Newton-Wellesley Hospital, 2014 Washington Street, Newton, MA 02462.	220101	10/26/2006	MA ..	ACS.
Mobile Infirmary Medical Center, 5 Mobile Infirmary Circle, Mobile, AL 36007.	010113	10/27/2006	AL ...	ASMBS.
Maine Medical Center, 22 Bramhall Street, Portland, ME 04102.	200009	11/06/2006	ME ..	ASMBS.
Magee Womens Hospital of UPMC, 3000 Halket Street, Pittsburgh, PA 15213.	390114	11/13/2006	PA ...	ASMBS.
Saint Francis Hospital and Medical Center, 114 Woodland Street, Hartford, CT 06105.	070002	11/15/2006	CT ...	ASMBS.
South Jersey Healthcare-Regional Medical Center, 1505 West Sherman Avenue, Vineland, NJ 08360.	310032	11/20/2006	NJ ...	ASMBS.
Overlook Hospital, 99 Beauvoir Avenue, Summit, NJ 07902.	310051	11/21/2006	NJ ...	Nursing Administration Office, ASMBS.
Cedars Medical Center, 1400 Northwest 12th Avenue, Miami, FL 33136.	100009	11/23/2006	FL ...	ASMBS.
Memorial Hermann Memorial City Hospital, 921 Gessner Road, Houston, TX 77024.	450610	11/27/2006	TX ...	ASMBS.
Tufts-New England Medical Center, 750 Washington Street, Boston, MA 02111.	220116	11/27/2006	MA ..	ASMBS.
Allegheny General Hospital, 320 East North Avenue, Pittsburgh, PA 15212.	390050	11/30/2006	PA ...	Fifth Floor, South Tower, ASMBS.
Northwest Medical Center, 2801 North State Road 7, Margate, FL 33063.	100189	11/30/2006	FL ...	ASMBS.
Potomac Hospital, 2300 Opitz Boulevard, Woodbridge, VA 22191.	490113	11/30/2006	VA ...	ASMBS.
Baptist Health Medical Center-Little Rock, 9601 I–630, Exit 7, Little Rock, AR 72205.	040114	12/01/2006	AR ...	ASMBS.
University of Washington Medical Center, 1959 NE Pacific Street, PO Box 356151, Seattle, WA 98195–6151.	1326002049	12/05/2006	WA ..	ACS.
St. Luke's Regional Medical Center, 333 North 1st Street, Suite 120, Boise, ID 83702.	130006	12/06/2006	ID	ASMBS.

Facility name	Provider No.	Date approved	State	Other information
University of Alabama at Birmingham Hospital, 1530 3rd Avenue South, Kracke Building 404, Birmingham, AL 35294–0016.	010033	12/07/2006	AL ...	ACS.
Hackensack University Medical Center, 30 Prospect Avenue, Hackensack, NJ 07601.	310001	12/08/2006	NJ ...	ACS.
Hialeah Hospital, 651 East 25th Street, Hialeah, FL 33013.	100053	12/13/2006	FL ...	ASMBS.
Sts. Mary and Elizabeth Hospital, 1850 Bluegrass Avenue, Louisville, KY 40215.	180040	12/15/2006	KY ...	Bariatric Office, ASMBS.
Bon Secours Surgical Weight Loss-Maryview Medical Center, 3636 High Street, Portsmouth, VA 23707.	490017	12/18/2006	VA ...	ASMBS.
Pomerado Hospital, 15615 Pomerado Road, Poway, CA 92064.	050636	12/18/2006	CA ...	ASMBS.
Boston Medical Center, 88 E. Newton Street, D507-Department of Surgery, Boston, MA 02118.	220031	12/19/2006	MA ..	ACS.
Medcenter One, Inc., 300 North 7th Street, Bismarck, ND 58501.	350015	12/19/2006	ND ..	ASMBS.
Meriter Hospital, 202 South Park Street, Madison, WI 53715.	520089	12/19/2006	WI ...	ASMBS.
University of Wisconsin Hospital & Clinics, 600 Highland Avenue, Madison, WI 53792.	520098	12/19/2006	WI ...	ASMBS.
Women and Children's Hospital, 4200 Nelson Road, Lake Charles, LA 70605.	190201	12/19/2006	LA ...	ASMBS.
Mount Carmel West Hospital, 793 West State Street, Columbus, OH 43222.	360035	12/20/2006	OH ..	ASMBS.
Southcoast Hospitals Group-Tobey Hospital, 43 High Street, Wareham, MA 02571.	220074	12/21/2006	MA ..	ASMBS.
Carilion Roanoke Memorial Hospital, 1906 Belleview Avenue, Roanoke, VA 24014.	N/A	12/26/2006	VA ...	ASMBS.
Mercy General Health Partners, 1500 Sherman Boulevard, Muskegon, MI 49444.	230004	12/26/2006	MI	ASMBS.
Mountainside Hospital, 1 Bay Avenue, Montclair, NJ 07042.	310054	12/26/2006	NJ ...	ASMBS.
Park Plaza Hospital, 1313 Hermann Drive, Houston, TX 77004.	450659	01/09/2007	TX ...	ASMBS.
Renaissance Hospital Houston, 2807 Little York, Houston, TX 77093.	450795	01/12/2007	TX ...	ASMBS.
Penn State Milton S. Hershey Medical Center, 500 University Drive, Hershey, PA 17033.	390256	01/18/2007	PA ...	ASMBS.
Shawnee Mission Medical Center, 9100 West 74th Street, Shawnee Mission, KS 66204.	170104	01/24/2007	KS ...	ASMBS.
Morristown Memorial Hospital, 100 Madison Avenue, Morristown, NJ 07962.	31–0015	01/25/2007	NJ ...	ACS.
Alvarado Hospital, 6655 Alvarado Road, San Diego, CA 92120.	050583	01/26/2007	CA ...	Alvarado Surgical Weight-Loss Program, ASMBS.
St. Francis Hospital, 7th and Clayton Streets, Wilmington, DE 19805.	080003	01/29/2007	DE ...	ASMBS.
Sacred Heart Medical Center, 101 West 8th Avenue, Spokane, WA 99220.	500054	02/05/2007	WA ..	ASMBS.
Ochsner Clinic Foundation, 1514 Jefferson Highway, New Orleans, LA 70121.	190036	02/06/2007	LA ...	ASMBS.
Northwest Specialty Hospital, 1593 East Polston Avenue, Post Falls, ID 83854.	130066	02/07/2007	ID	ASMBS.
Sacred Heart Hospital, 421 Chew Street, Allentown, PA 18102.	390197	02/07/2007	PA ...	ASMBS.
Rio Grande Regional Hospital, 101 East Ridge Road, McAllen, TX 78503.	450711	02/12/2007	TX ...	ASMBS.
Gundersen Lutheran Medical Center, 1900 South Avenue, La Crosse, WI 54601.	520087	02/13/2007	WI ...	ASMBS.
Kettering Medical Center, 3535 Southern Boulevard, Kettering, OH 45429.	360079	02/16/2007	OH ..	ASMBS.
Beth Israel Deaconess Medical Center, 330 Brookline Avenue, Boston, MA 02215.	N/A	02/17/2006	MA ..	ACS.
Shady Grove Adventist Hospital, 9901 Medical Center Drive, Rockville, MD 20850.	210057	02/19/2007	MD ..	ASMBS.
Pitt County Memorial Hospital, 2100 Stantonsburg Road, Greenville, NC 27835.	340040	02/20/2007	NC ..	ASMBS.
St. Cloud Hospital, 1406 Sixth Avenue, North, St. Cloud, MN 56303.	240036	02/23/2007	MN ..	ASMBS.
Virginia Mason Medical Center, 1100 Ninth Avenue, Seattle, WA 98101.	500005	03/01/2007	WA ..	ASMBS.
Southeast Georgia Health System, 2415 Parkwood Drive, Brunswick, GA 31520.	110025	03/06/2007	GA ..	ASMBS.

Facility name	Provider No.	Date approved	State	Other information
Baystate Medical Center, 759 Chestnut Street, Springfield, MA 01199.	220077	03/13/2007	MA ..	ACS.
PinnacleHealth Community Campus, 4300 Londonderry Road, c/o PO Box 8700, Harrisburg, PA 17109.	390067	03/29/2007	PA ...	ASMBS.
The Valley Hospital, 223 North Van Dien Avenue, Ridgewood, NJ 07450.	310012	03/30/2007	NJ ...	ASMBS.
Charleston Area Medical Center, 800 Pennsylvania Avenue, Charleston, WV 25302.	510022	04/16/2007	WV ..	ASMBS.
Presbyterian Hospital of Dallas, 8200 Walnut Hill Lane, Dallas, TX 75231.	450462	04/16/2007	TX ...	ASMBS.
Dekalb Medical Center, 2701 North Decatur Road, Decatur, GA 30033.	110076	04/26/2007	GA ..	ASMBS.
St. Francis Health Center, 1700 SW 7th Street, Topeka, KS 66606.	170016	04/26/2007	KS ...	ASMBS.
St. Mark's Hospital, 1200 East 3900 South, Salt Lake City, UT 84124.	47007	04/26/2007	UT ...	ASMBS.
Faulkner Hospital, 1153 Centre Street, Boston, MA 02130.	220119	04/27/2007	MA ..	ACS.
George Washington University Hospital, 9000 23rd Street, NW., Washington, DC 20037.	090001	08/14/2006	DC ..	ASMBS.
William Beaumont Hospital—Royal Oak, 3601 West Thirteen Mile Road, Royal Oak, MI 48073–6769.	230130	04/20/2007	MI	ACS.
University Medical Center at Princeton, 253 Witherspoon Street, Princeton, NJ 08542.	N/A	02/24/2006	NJ ...	ASMBS.
Del Sol Medical Center, 10201 Gateway West, Suite 130, El Paso, TX 79925.	45–0646	05/03/2007	TX ...	ACS.
Winchester Hospital, 41 Highland Avenue, Winchester, MA 01890.	220105	05/31/2007	MA ..	ASMBS.
Lawrence Memorial Hospital—Hallmark Health System, 170 Governors Avenue, Medford, MA 02155.	220070	05/31/2007	MA ..	ASMBS.
The Methodist Hospital, 6565 Fannin, NB1–001, Houston, TX 77030.	450358	03/22/2007	TX ...	ACS.
ValleyCare Health System, 1111 East Stanley Boulevard, Livermore, CA 94550.	050283	06/07/2007	CA ...	ASMBS.
The Presbyterian Hospital, 200 Hawthorne Lane, Charlotte, NC 28204.	340053	06/06/2007	NC ..	ASMBS.
Nix Hospital, 414 Navarro Street, San Antonio, TX 78205	450130	06/08/2007	TX ...	ASMBS.
Huntsville Hospital, 101 Sivley Road, Huntsville, AL 35801.	010039	05/11/2007	AL ...	ASMBS.
The Jewish Hospital, 4777 Galbraith Road, Cincinnati, OH 45236.	360016	06/07/2007	OH ..	ASMBS.
UCI Medical Center, 101 The City Drive South, Orange, CA 92868.	050348	05/25/2007	CA ...	ACS.
Kaiser Permanente Medical Center Richmond, 901 Nevin Avenue, Richmond, CA 94801.	050075	05/24/2007	CA ...	ACS.
Green Hospital, 12395 El Camino Real, San Diego, CA 92130.	050424	06/21/2007	CA ...	ASMBS.
Sutter Roseville Medical Center, One Medical Plaza, Roseville, CA 95661.	050309	06/22/2007	CA ...	ASMBS.
Munroe Regional Medical Center, 1500 Southwest 1st Avenue, Ocala, FL 34471.	100062	06/05/2007	FL ...	ASMBS.
Enloe Medical Center, 251 Cohasset Road, Chico, CA 95926.	050039	06/11/2007	CA ...	ASMBS.
St. Francis Hospital & Health Centers, 1600 Albany Street, Beech Grove, IN 46107.	150033	06/15/2007	IN	ASMBS.
Southern Surgical Hospital, 1700 West Lindberg Drive, Slidell, LA 70458.	190270	06/21/2007	LA ...	ASMBS.
Creighton University Medical Center, 601 North 30th Street, Omaha, NE 68131.	280030	06/20/2007	NE ...	ASMBS.
Peninsula Regional Medical Center, 100 East Carroll Street, Salisbury, MD 21801.	210019	06/20/2007	MD ..	ASMBS.
Wadley Regional Medical Center, 1000 Pine Street, Texarkana, TX 75501.	450200	06/08/2007	TX ...	ASMBS.
Vista Medical Center Hospital, 4301 Vista Road, Pasadena, TX 77504.	450831	06/22/2007	TX ...	ASMBS.
St. David's Medical Center, 919 East 32nd Street, Austin, TX 78705.	450531	06/22/2007	TX ...	ASMBS.
Sanford USD Medical Center, 1305 West 18th Street, Sioux Falls, SD 57117.	430027	01/17/2006	SD ...	ASMBS.
Weight Loss Surgery Program at Baylor, 3600 Gaston Avenue, Suite 360 Wadley Tower, Dallas, TX 75246.	N/A	06/20/2007	TX ...	ASMBS.
Shelby Baptist Medical Center, 1000 First Street N., Alabaster, AL 35007.	010016	05/18/2007	AL ...	ACS.

Facility name	Provider No.	Date approved	State	Other information
Lehigh Valley Hospital and Health Network, Cedar Crest & I–78, PO Box 689, Allentown, PA 18105–1556.	390133	05/29/2007	PA ...	ACS.
West Hills Hospital, 7300 Medical Center Drive, West Hills, CA 91307.	050481	06/27/2007	CA ...	ASMBS.
Adirondack Medical Center, 2233 State Route 86, Saranack Lake, NY 12983.	330079	06/26/2007	NY ...	ASMBS.
Middletown Regional Hospital, 105 McKnight Drive, Middletown, OH 45044.	360076	06/25/2007	OH ..	ASMBS.
Kaleida Health, Buffalo General, 100 High Street, Buffalo, NY 14203.	300005	06/25/2007	NY ...	ASMBS.
Miami Valley Hospital, One Wyoming Street, Dayton, OH 45409.	N/A	06/25/2007	OH ..	ASMBS.
Minimally Invasive Surgery Hospital, 11217 Lakeview Avenue, Lenexa, KS 66219.	N/A	06/25/2007	KS ...	ASMBS.
Saint Agnes Medical Center, 1303 E. Herndon Avenue, Fresno, CA 93720.	05–0093	07/24/2007	CA ...	ASMBS.
Sartori Memorial Hospital, 515 College Street, Cedar Falls, IA 50613.	160040	07/17/2007	IA	ASMBS.
Maimonides Medical Center, 948 48th Street, 2nd floor, Brooklyn, NY 11219.	33–0194	07/10/2007	NY ...	ASMBS.
Westchester Medical Center, 95 Grasslands Road, Valhalla, NY 10595.	330234	07/17/2007	NY ...	ASMBS.
Deaconess Hospital, 311 Straight Street, Cincinnati, OH 45219.	36–0038	07/17/2007	OH ..	ASMBS.
Northern Ohio Bariatric Center at Parma Hospital, 6305 Powers Boulevard, Parma, OH 44129.	360041	07/10/2007	OH ..	ASMBS.
Einstein at Elkins Park, 60 E. Township Line Road, Elkins Park, PA 19027.	390142	07/10/2007	PA ...	ASMBS.
Lahey Clinic Medical Center, 41 Mall Road, Burlington, MA 01805.	220171	06/22/2007	MA ..	ACS.
St. Francis Hospital, 34515 Ninth Ave South, Federal Way, WA 98003.	500141	07/26/2007	WA ..	ACS.
California Foundation for Health, 1401 Garces Highway, Delano, CA 93215.	050608	07/10/2007	CA ...	d.b.a. Delano Regional Medical Center; ASMBS.
Northeast Alabama Regional Medical Center, 400 East 10th Street, Anniston, AL 36207.	010078	07/30/2007	AL ...	ASMBS.
Trinity Medical Center, 4343 N. Josey Lane, Carrollton, TX 75010.	45–0730	07/30/2007	TX ...	ASMBS.
Gratiot Medical Center, 300 E. Warwick Drive, Alma, MI 48801.	23–0030	07/30/2007	MI	ASMBS.
Cuyuna Regional Medical Center, 320 East Main Street, Crosby, MN 56441.	241353	08/20/2007	MN ..	ASMBS.
Valley Medical Center, 400 South 43rd Street, Renton, WA 98055.	500088	07/30/2007	WA ..	ASMBS.
Renaissance Hospital Dallas, 427 W. 20th Street, Suite 300, Houston, TX 77008.	670002	08/08/2007	TX ...	ASMBS.
UPMC Presbyterian Shadyside, 5230 Centre Avenue, Pittsburgh, PA 15232.	39–0114	08/20/2007	PA ...	ASMBS.
Clarian North Medical Center, 6625 Network Way, Suite 100, Indianapolis, IN 46202.	15–0161	08/20/2007	IN	ASMBS.
Genesis Medical Center, 1227 East Rusholme Street, Davenport, IA 52803.	160033	08/08/2007	IA	ASMBS.
University General Hospital, 7501 Fannin Street, Houston, TX 77054.	670019	08/08/2007	TX ...	ASMBS.
Ellis Hospital, 1101 Nott Street, Schenectaday, NY 12308	330153	06/19/2007	NY ...	ASMBS.
University of Texas Medical Branch, 301 University Boulevard, Galveston, TX, 77555–1168.	450018	08/16/2007	TX ...	ACS.
UPMC Presbyterian Shadyside, 5230 Centre Avenue, Pittsburgh, PA 15232.	39–0114	08/20/2007	PA ...	ABMS.
Christiana Care Health Services, 4755 Ogletown—Stanton Road, Newark, DE 19718.	080001	08/29/2007	DE ...	ASMBS.
Stanford Hospital and Clinics, 300 Pasteur Drive, Stanford, CA 94305.	050441	09/13/2007	CA ...	ACS.
Summa Health Systems Hospital, 95 Arch Street, Suite 240, Akron, OH 44304.	360020	09/21/2007	OH ..	ASMBS.
Memorial Regional Hospital, 3500 Johnson Street, Hollywood, FL 33021.	100038	09/11/2007	FL ...	ASMBS.
Temple University Hospital, 3401 North Broad Street, Philadelphia, PA 19140.	390027	09/21/2007	PA ...	ASMBS.
Good Samaritan Hospital, 2425 Samaritan Drive, San Jose, CA 95124.	50380	09/21/2007	CA ...	ASMBS.
Johnson City Medical Center, 400 North State of Franklin Road, Johnson City, TN 37604.	HSP440063	09/27/2007	TN ...	ASMBS.

Facility name	Provider No.	Date approved	State	Other information
Providence Saint Joseph Medical Center, 201 South Buena Vista Street, Suite 425, Burbank, CA 91505.	50235	N/A	CA ...	ASMBS–09/17/2007; ACS–09/05/2007.
Baptist Bariatric Center of Excellence, 1000 West Moreno Street, Pensacola, FL 32501.	10–0093	09/27/2007	FL ...	ASMBS.
Hillcrest Hospital, 2104 Woodruff Road, Greenville, SC 29607.	43–0037	10/10/2007	SC ...	ASMBS.
Fairway Medical, 67252 Industry Lane, Covington, LA 70433.	190267	10/10/2007	LA ...	ASMBS.
John T. Mather Memorial Hospital, 75 North Country Road, Port Jefferson, NY 11777.	JTM 33–0185	10/10/2007	NY ...	ASMBS.
Lenox Hill Hospital, 110 East 59th Street, Suite 8A, New York, NY 10022.	10003F8	10/10/2007	NY ...	ASMBS.
Easton Hospital, 250 South 21st Street, Easton, PA 18042.	390162	10/10/2007	PA ...	ASMBS.
Medical City Dallas Hospital, 7777 Forest Lane, Suite 240A, Dallas, TX 75230.	000340	10/10/2007	TX ...	ASMBS.
St Vincent's East, 50 Medical Park East Drive, Birmingham, AL 35235.	010011	10/10/2007	AL ...	ASMBS.
Northside Hospital, 1000 Johnson Ferry Road, Atlanta, GA 30342.	11–0161	10/10/2007	GA ..	ASMBS.
Missouri Bariatric Services, 1000 W. Nifong Boulevard, Building 2, Suite 210, Columbia, MO 65203.	000011108	10/10/2007	MO ..	ASMBS.
Presbyterian Hospital of Plano, 6200 West Parker Road, Plano, TX 75093.	45–0771	10/10/2007	TX ...	ASMBS.
Norton Suburban Hospital, 315 East Broadway, Louisville, KY 40202.	180088	10/10/2007	KY ...	ASMBS.
Sky Ridge Medical Center, 10101 RidgeGate Parkway, Lone Tree, CO 80124.	060112	10/30/2007	CO ..	ASMBS.
St. Mary Medical Center, 1050 Linden Avenue, Long Beach, CA 90813.	050191	10/30/2007	CA ...	ASMBS.
Scott and White Hospital, 2401 S. 31st Street, Temple, TX 76508.	450054	10/24/2007	TX ...	ACS.
The Methodist Hospitals, Inc., 303 East 89th Avenue, Merrillville, IN 46410.	150132	10/30/2007	IN	ASMBS.
Parkview Community Hospital, 3865 Jackson Street, Riverside, CA 92503.	050102	10/30/2007	CA ...	ASMBS.
Evergreen Hospital, 12040 NE 128th Street, Kirkland, WA 98034.	500124	10/30/2007	WA ..	ASMBS.
University of Maryland, Medical Center, 22 South Greene Street, Baltimore, MD, 21201–1595.	21002	11/05/2007	MD ..	ACS.
Montefiore Medical Center, 111 East 210th Street, Bronx, NY 10467.	330059	11/07/2007	NY ...	Group #: 330059, Dr. Karen Gibbs #: 140341, Dr. Pratibha Vemulapalli #: 3097H1; ACS.
Emory Crawford Long Hospital, 1364 Clifton Road, NE, Atlanta, GA 30322.	110078	11/13/2007	GA ..	ACS.
El Camino Hospital, 2500 Grant Road, Mountain View, CA 94039.	050308	11/19/2007	CA ...	ASMBS.
Northeast Baptist Hospital, 8811 Village Drive, San Antonio, TX 78217.	450058	11/19/2007	TX ...	ASMBS.
University of Iowa Hospitals and Clinics, 4624 JCP Bariatric Surgery, Iowa City, IA 52242.	160058	11/19/2007	IA	ASMBS.
El Camino Hospital, 2500 Grant Road, Mountain View, CA, 94039.	050308	11/19/2007	CA ...	ASMBS.
Aspirus Wausau Hospital, 333 Pineridge Boulevard, Wausau, WI 54401.	52–0030	11/28/2007	WI ...	ASMBS.
Eastern Idaho Regional Medical Center, 2860 Channing Way, Suite 102, Idaho Falls, ID 83404.	13–0018	12/10/2007	ID	ASMBS.
Mount Sinai Medical Center, 4701 North Meridian Avenue, Miami Beach, FL 33140.	10–0034	12/11/2007	FL ...	ASMBS.
North Florida Regional Medical Center, 6400 Newberry Road, Suite 106, Gainesville, FL 32605.	21536	12/27/2007	FL ...	ASMBS.
Baylor Regional Medical Center at Plano, 470 Alliance Boulevard, Plano, TX 75093.	45–0890	01/04/2008	TX ...	ASMBS.
Memorial Medical Center, 1800 Coffee Road, Suite 30, Modesto, CA 95350.	050557	01/04/2008	CA ...	ASMBS.
Pennsylvania Hospital, 800 Spruce Street, 2 Cathcart, Philadelphia, PA 19107.	39–0226	01/08/2008	PA ...	ASMBS.
Houston Northwest Medical Center, 710 FM 1960 Road West, Houston, TX 77090.	450638	01/08/2008	TX ...	ASMBS.
St. Bernadine Medical Center, 2101 North Waterman Avenue, San Bernadino, CA 92404.	05–0129	01/04/2008	CA ...	ASMBS.
UCLA Medical Center, 10833 Le Conte Avenue, CHS 72–236, Los Angeles, CA 90095.	050262	01/08/2008	CA ...	ASMBS.

Facility name	Provider No.	Date approved	State	Other information
Lourdes Medical Center Burlington County, 218–A Sunset Road, Willingboro, NJ 08046.	310061	01/30/2008	NJ ...	ASMBS.
Sacred Heart Medical Center, 1200 Hilyard Street, Suite S–570, Eugene, OR 97401.	380033	01/23/2008	OR ..	ASMBS.
Salt Lake Regional Medical Center, 1050 East South Temple, Salt Lake City, UT 84102.	460003	02/11/2008	UT ...	ASMBS.
Kaiser Permanente-South San Francisco, 1200 El Camino Real, South San Francisco, CA 94080.	050070	01/30/2008	CA ...	ASMBS.
Chilton Memorial Hospital, 97 West Parkway, Pompton Plains, NJ 07444.	310017	02/12/2008	NJ ...	ASMBS.
Mary Imogene Bassett Hospital, One Atwell Road, Cooperstown, NY 13326.	330136	02/12/2008	NY ...	ASMBS.
Sharp Memorial Hospital, 7901 Frost Street—5 South /ACC, San Diego, CA 92123.	0150100	02/11/2008	CA ...	ASMBS.
Doctors Hospital at White Rock Lake, 9440 Poppy Drive, Dallas, TX 75218.	450678	01/30/2008	TX ...	ASMBS.
Rhode Island Hospital, 2 Dudley Street, Suite 470, Providence, RI 02905.	410007	02/25/2008	RI	ASMBS.
Munson Medical Center, 1105 Sixth Street, Traverse City, MI 49684.	23–0097	02/19/2008	MI	ASMBS.
DayOne Health at 900 N. Michigan Surgical Center, 409 West Huron, Suite 300, Chicago, IL 60613.	538810	02/19/2008	IL	ASMBS.
USC University Hospital, 1500 San Pablo, Los Angeles, CA 90033.	05–0696	01/30/2008	CA ...	ASMBS.
Lexington Medical Center, 2720 Sunset Boulevard, West Columbia, SC 29169–4810.	See other information	01/14/2008	SC ...	ACS; NPI: Hospital Services 1356366314; Professional Services 1144248097.
Saint Clare's Hospital, 400 West Blackwell Street, Dover, NJ 07801.	310050	03/17/2008	NJ ...	ASMBS.
Hartford Hospital, 85 Seymour Street, Suite 415, Hartford, CT 06106.	07–0025	03/25/2008	CT ...	ASMBS.
Singing River Hospital, 2809 Denny Avenue, Pascagoula, MS 39581.	250040	03/17/2008	MS ..	ASMBS.
St. John's Regional Health Center, 1235 East Cherokee Street, Springfield, MO 65804.	260065	03/17/2008	MO ..	ASMBS.
Willis Knighton Health System, 2551 Greenwood Road, Suite 340, Shreveport, LA 71103.	190111	03/17/2008	LA ...	ASMBS.
Cottage Health System, PO Box 689 Pueblo at Bath Street, Santa Barbara, CA 93102–0689.	030596	02/25/2008	CA ...	ASMBS.
Syosset Hospital, 221 Jericho Turnpike, Syosset, NY 11791.	330106	02/19/2008	NY ...	ASMBS.
The Hospital of Central Connecticut, 1000 Grand Street, New Britain, CT 06050.	070035	03/11/2008	CT ...	ASMBS.
Stringfellow Memorial Hospital, 105 Windsor Lane, Rainbow City, AL 35906.	01–0038	03/11/2008	AL ...	ASMBS.
Providence Alaska Medical Center, 3200 Providence Drive, Anchorage, AK 99519–6604.	02–0001	03/17/2008	AK ...	ASMBS.
The Reading Hospital and Medical Center, 2603 Keiser Boulevard, Wyomissing, PA 19610.	390044	03/25/2008	PA ...	ASMBS.
Good Samaritan Hospital, 255 Lafayette Avenue, Suffern, NY 10901.	330158	03/25/2008	NY ...	ASMBS.
San Joaquin Community Hospital, 2819 H Street, Bakersfield, CA 93301.	04055	04/01/2008	CA ...	ASMBS.
Lowell General Hospital, 295 Varnum Avenue, Lowell, MA 01854.		02/22/2008	MA ..	Medicare: 220063; Medicaid Inpatient #: 100228; Medicaid Outpatient #: 1201069; ACS.
Memorial Health University Medical Center, 4700 Waters Avenue, Savannah, GA 31404.	11–0036	04/08/2008	GA ..	ASMBS.
Abington Memorial Hospital, 1235 Old York Road, Suite G–28, Abington, PA 19001.	390231	04/21/2008	PA ...	ASMBS.
Christiana Care Health Services, 3506 Kennett Pike, Wilmington, DE 19807.	080001	04/18/2008	DE ...	ACS.

Addendum XVI—FDG–PET for Dementia and Neurodegenerative Diseases Clinical Trials

In a National Coverage Determination for fluorodeoxyglucose positron emission tomography (FDG–PET) for Dementia and Neurodegenerative Diseases (220.6.13) we indicated that an FDG–PET scan is considered reasonable and necessary in patients with mild cognitive impairment or early dementia only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use, and evaluation of the FDG–PET scan.

Facility name	Provider No.	Date approved	State	Name of trial	Principal investigator
UCLA Medical Center, 10833 Le Conte Avenue, Los Angeles, CA 90095.	HW13029	06/07/2006	CA	Early and Long-Term Value of Imaging Brain Metabolism.	Dr. Daniel Silverman.
Santa Monica-UCLA Medical Center, 1245 16th Street, Suite 105, Santa Monica, CA 90404.	W11817A	01/12/2007	CA	N/A	N/A.
University of Buffalo, 3435 Main Street, Buffalo, NY 14214.	14414A	03/12/2007	NY	Metabolic Cerebral Imaging in Incipient Dementia (MCI–ID).	Dr. Daniel Silverman.

[FR Doc. E8–13110 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

Federal Register

Friday,
June 27, 2008

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, and 491

Medicare Program; Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, and 491

[CMS–1910–P2]

RIN 0938–AJ17

Medicare Program; Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish location requirements including exception criteria for rural health clinics (RHCs). It would also require RHCs to establish a quality assessment and performance improvement (QAPI) program. In addition, it would: Clarify our policies on ''commingling'' of an RHC with another entity; revise the RHC and Federally Qualified Health Centers (FQHC) payment methodology and exceptions to the per-visit payment limit to implement statutory requirements; revise RHC and FQHC payment requirements for services furnished to skilled nursing facility (SNF) patients; allow RHCs to contract with RHC nonphysician providers under certain circumstances; and update the regulations pertaining to waivers to the staffing requirements. This proposed rule would also add requirements for RHCs and FQHCs to maintain and document an infection control process and to post RHC or FQHC hours of clinical services. In addition, this proposed rule would update the requirements under the emergency services standard and patient health records condition for certification (CfC) to reflect advancements in technology and treatment. Finally, this proposed rule solicits comments on payment for high cost drugs and the appropriateness of a mental health specialty clinic as an exception to the location requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 26, 2008.

ADDRESSES: In commenting, please refer to file code CMS–1910–P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' and enter the CMS–1910–P2 to find the document accepting comments.

2. *By regular 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–1910–P2, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1910–P2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(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.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Corinne Axelrod, (410) 786–5620. Rural health clinic location requirements and exceptions, staffing and payment. Mary Collins, (410) 786–3189 and Scott Cooper (410) 786–9465. Quality assessment and performance improvement and health and safety standards.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Abbreviations and Acronyms

AED—Automated External Defibrillator
BBA—Balanced Budget Act of 1997
BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CAH—Critical Access Hospital
CDC—Centers for Disease Control and Prevention
CfC—Condition for Certification
CMS—Centers for Medicare & Medicaid Services
CNM—Certified Nurse-Midwife
CNS—Clinical Nurse Specialist
CoP—Condition of Participation
CP—Clinical Psychologist
CSW—Clinical Social Worker
DRA—Deficit Reduction Act
DSMT—Diabetes Self-Management Training
FI—Fiscal Intermediary
FQHC—Federally Qualified Health Center
GAO—Government Accountability Office
GDSC—Governor-Designated and Secretary-Certified Shortage Areas
HHS—Department of Health and Human Services
HPSA—Health Professional Shortage Area
HRSA—Health Resources and Services Administration
MAC—Medicare Administrative Contractor

MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MUA—Medically Underserved Area
MUP—Medically Underserved Population
NP—Nurse Practitioner
OBRA—Omnibus Budget Reconciliation Act
OIG—Office of the Inspector General
OMB—Office of Management and Budget
PA—Physician Assistant
PHS—Public Health Service
PPS—Prospective Payment System
PRA—Paperwork Reduction Act
QAPI—Quality Assessment and Performance Improvement
RFA—Regulatory Flexibility Act
RHC—Rural Health Clinic
RO—Regional Office
RUCA—Rural Urban Commuting Area
SCHIP—State Children's Health Insurance Program
SNF—Skilled Nursing Facility
UA—Urbanized Area
UIC—Urban Influence Code
USDA—United States Department of Agriculture

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I. Background

A. Publication and Suspension of the December 24, 2003 Final Rule

On February 28, 2000, we published a proposed rule in the **Federal Register** (65 FR 10450) entitled ''Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program.'' This proposed rule revised certification and payment requirements for rural health clinics (RHCs) as required by the Balanced Budget Act of 1997 (BBA), Public Law 105–33, enacted on August 5, 1997. We issued the final RHC rule on December 24, 2003 (68 FR 74792).

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted. Section 902 of the MMA amended section 1871(a) of the Social Security Act (the Act) and requires the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that ''[s]uch timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances.''

To comply with the MMA requirement to publish a final rule not more than 3 years after a proposed rule, we suspended the effectiveness of the December 24, 2003 final rule on September 22, 2006 (71 FR 55341). The Code of Federal Regulations currently reflects the regulations in effect before December 2003.

While section 902 of the MMA did not explicitly prohibit the Secretary from finalizing all proposed rules that were published as an interim or proposed rule more than 3 years before December 8, 2003, we chose to take this opportunity to propose additional updates and clarifications of the provisions published in the previous rule, and provide the public with the opportunity to comment on these proposals.

B. Summary of the Provisions of the December 24, 2003 Final Rule

The December 24, 2003 final rule addressed comments received on the February 28, 2000 proposed rule, and finalized policies regarding RHC and federally qualified health center (FQHC) payment and participation in the Medicare program. It established: (1) Criteria and a process to decertify RHCs which no longer serve rural or medically underserved areas (MUAs), as required by the BBA; (2) a policy that would have prohibited the commingling of RHC resources with another entity's resources; and (3) a requirement that RHCs establish a quality assessment and performance improvement (QAPI) program.

The December 24, 2003 final rule also updated payment policies and regulations to conform to statutory requirements of the Omnibus Budget Reconciliation Acts (OBRA) '86, '87, '89, and '90 and the MMA.

For the reasons specified in section I.A. of this proposed rule, these provisions have been suspended.

C. Origin of the RHC/FQHC Programs

The Rural Health Clinic Services Act of 1977 (Pub. L. 95–210) enacted on December 13, 1977, amended the Act by adding section 1861(aa) of the Act to extend Medicare and Medicaid entitlement and payment for primary and emergency care services furnished at an RHC by physicians and certain ''nonphysician practitioners,'' and for services and supplies incidental to their services. ''Nonphysician practitioners'' included nurse practitioners (NPs) and physician assistants (PAs). (Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists (CPs), clinical social workers (CSWs), and certified nurse-midwives (CNMs).)

According to House Report No. 95–548(I), the purpose of the Rural Health Clinic Services Act was to address an inadequate supply of physicians serving Medicare beneficiaries and Medicaid recipients in rural areas. The legislation addressed this problem by authorizing CMS and States to pay qualifying clinics on a cost-related basis for providing Medicare beneficiaries and Medicaid recipients, respectively, with outpatient physician and certain nonphysician services. (The Medicare payment provisions for RHCs are in sections 1833(a)(3) and 1833(f) of the Act and in regulations at § 405.2462 through § 405.2468.) Payment to RHCs for services furnished to beneficiaries is

made on the basis of an all-inclusive payment methodology subject to a maximum payment per-visit and annual reconciliation.

Qualifying clinics, among other criteria, must be located in an area that is determined to be nonurbanized by the U.S. Census Bureau. The clinic also must be located in an area designated as a shortage area either by the Health Resources and Services Administration (HRSA) or by the chief executive officer of the State and certified by the Secretary, Department of Health and Human Services (HHS). (See section 1861(aa)(2) of the Act, following subparagraph (K).)

Qualifying clinics also must employ a PA or NP and, to meet requirements of the OBRA '89, must have a NP, a PA, or a CNM available to furnish patient care services at least 5.0 percent of the time the RHC operates.

The FQHC Medicare coverage and payment benefit was provided for in OBRA '90, Public Law 101–508, enacted on November 5, 1990, and implemented in the **Federal Register** (57 FR 24961) on June 12, 1992. On April 3, 1996, we published a final regulation (61 FR 14640) that addressed the issues raised by commenters on the June 1992 rule.

OBRA '90 defines an FQHC as an entity that is receiving a grant under section 329, section 330, or section 340 of the Public Health Service Act (PHS). The definition of an FQHC was expanded by section 13556(a)(3) of OBRA '93 (Pub. L. 103–66) enacted on August 10, 1993, effective as if included in OBRA '90 on October 1, 1991. The expanded definition included outpatient programs or facilities operated by a tribal organization under the Indian Self-Determination Act, or by an urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act.

The FQHC scope of benefits for core services is similar to the RHC benefit, that is, physician, nonphysician practitioner, and mental health professional services. The FQHC benefit also includes a number of preventive services.

Each FQHC is reimbursed its reasonable costs based on an all-inclusive per-visit methodology subject to tests of reasonableness, and is subject to an overall payment limit similar to RHCs. The national FQHC payment limit is based on the costs of providing primary care physician and prevention services. For FQHC services, there are two upper payment limits: One limit is for centers located in urban areas and the other is for centers located in rural areas.

D. Growth of the RHC Program

The RHC program has grown from less than 1,000 Medicare-approved RHCs in 1992 to more than 3,700 in 2008. However, since 2001, growth in the program has leveled off. While part of this increase has improved access to primary care services in rural areas for Medicare beneficiaries and Medicaid recipients, there are instances in which these additional RHCs have not expanded access.

1. Continuing Participation

A significant factor in the growth of RHCs stems from the original (pre-BBA) RHC legislation, which included a ''grandfather clause'' to promote the development of RHCs. (See section 1(e) of the Health Clinic Services Act of 1977 (Pub. L. 95–210) enacted December 13, 1977, 42 U.S.C. 1395x note. Also see § 491.5(b)(2) of the regulations.) Section 1861(aa)(2) of the Act stated that any RHC that subsequently failed to satisfy the requirements pertaining to the rural and underserved location requirement still would be deemed to have satisfied the requirement of that clause.

These provisions protected the clinics' RHC status regardless of any changes to the rural or underserved status of the service areas. It allowed clinics to remain in the RHC program even though the service areas no longer were considered rural or medically underserved.

The Congress established these protections to encourage clinics to attract needed health care professionals to underserved rural areas and to retain them without being concerned about losing the shortage area designation, which would make the clinics ineligible for RHC status and its reimbursement incentives. Once the clinic successfully attracted the needed health care professionals to the area, the Congress wanted to ensure that the service area did not return to its previous underserved status because we removed the clinic's RHC status and reimbursement incentives.

Although the grandfather clause provision was an appropriate policy at the time, we now have RHC participation in some service areas with extensive health care delivery systems that provide adequate access to primary care for Medicare beneficiaries and Medicaid recipients. Both the Government Accountability Office (GAO) and the HHS Office of the Inspector General (OIG) recommended the establishment of a mechanism, under the survey and certification process for Medicare facilities, to discontinue RHC status and its payment incentives in those service areas where they are no longer justified. In section 4205(d)(3) of the BBA, the Congress responded to these recommendations by amending the grandfather clause provision to provide protection only to clinics essential to the delivery of primary care in the respective service area.

2. Medically Underserved/Shortage Area Designations

Another reason for the continued growth of the RHC program was that two of the types of shortage area designations that are used for RHC certification, the medically underserved area (MUA) and the Governor-Designated Secretary-Certified Shortage Area (GDSC) designations, did not have a statutory requirement for regular review and were not reviewed systematically and updated after their initial designation. As a result, some RHCs are in areas that no longer would be designated as underserved if reviewed with current data. In response, the Congress amended the legislation in section 4205(d) of the BBA by requiring that only those clinics located in shortage areas that were designated or updated within the previous 3 years would qualify for purposes of the RHC program.

3. Expansion of Eligible Designations for RHC Certification

Section 6213 of OBRA '89 amended section 1861(aa)(2) of the Act to expand the types of shortage areas eligible for RHC certification. Until then, the eligible areas included only those designated by the Secretary as areas having a shortage of personal health services under section 330(b)(3) of the PHS Act (medically underserved areas (MUAs)) and those designated as geographic health professional shortage areas (HPSAs) under section 332(a)(1)(A) of the PHS Act. The OBRA '89 amendment expanded the eligible areas to also include: high impact migrant areas designated under section 329(a)(5) of the PHS Act; areas containing a population group HPSA designated under section 332(a)(1)(B) of the PHS Act; and areas designated by the Governor of a State and certified by the Secretary as having a shortage of personal health services. However, later, the Health Centers Consolidation Act of 1996 (Pub. L. 104–299) renumbered section 329 of the PHS Act and repealed the requirement for designation of high impact migrant areas.

4. Commingling

The growth of RHCs may have also been stimulated by the practice of

''commingling.'' The term ''commingling'' is used to describe the sharing of RHC space, staff, supplies, records, or other resources with a private Medicare practice or other entity operated by the same physician and nonphysician practitioners working for the RHC, during RHC hours of operation. We recognize that providing care in rural areas that have limited infrastructure and providers requires the coordination of scarce resources, and permit the sharing of resources in certain situations. In some of these situations, however, it is believed that commingling has been used to maximize Medicare payment by obtaining RHC status for an integrated practice that submits both RHC and non-RHC Medicare claims.

E. Government Reports on RHCs

The GAO report, ''Rural Health Clinics: Rising Program Expenditures Not Focused on Improving Care in Isolated Areas'' (GAO/HHS–97–24, November 22, 1996), and the HHS/IG report ''Rural Health Clinics: Growth, Access and Payment'' (OEI–05–94–00040, July 1996), both concluded that the growth of RHCs is not proportional to community need and that many RHCs no longer require cost-based reimbursement as a payment incentive. They also concluded that the payment methodology for provider-based RHCs lacks sufficient cost controls and recommended establishing payment limits and screens on reasonable costs for these providers. (A provider-based RHC is an integral and subordinate part of a Medicare participating hospital, critical access hospital (CAH), skilled nursing facility (SNF), or home health agency (HHA), and is operated with other departments of the provider under common governance, professional supervision, and usually licensure. All other RHCs are considered to be independent.)

In August 2005, the OIG issued a followup report, ''Status of the Rural Health Clinic Program'' (OEI–05–03–00170), which recommended that HRSA review shortage designations within the requisite 3-year period and publish regulations to revise its shortage designation criteria. The report also suggested that CMS issue regulations to: (1) Ensure that RHCs determined to be essential providers remain certified as RHCs; and (2) require prospective RHCs to document need on access to health care in rural underserved areas.

II. Provisions of This Proposed Rule

A. RHC Location Requirements and Exceptions

1. RHC Location Requirements

In sections 4205(d)(1) and (2) of the BBA, the Congress amended section 1861(aa)(2) of the Act. As revised, the statute states that RHCs may include only a facility which is located in: (1) A nonurbanized area, as defined by the U.S. Census Bureau; (2) an area in which there are an insufficient number of needed health care practitioners as determined by the Secretary; and (3) an area that has been designated or certified by the Secretary within the previous 3 years as having an insufficient number of needed health care practitioners.

Section 4205(d)(3)(A) of the BBA, which amended the third sentence of section 1861(aa)(2) of the Act, revised the ''grandfather clause'' that permitted an exception to the termination of RHC status for a clinic located in an area that is no longer a rural area or a shortage area. This revision specified that an exception was available only if the RHC was determined to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the RHC. These amendments were made effective upon issuance of implementing regulations that the Congress directed CMS to issue by January 1, 1999. The BBA requirement that every RHC must have a current shortage area designation (made or updated within the previous 3-year period), has been implemented for new RHCs through administrative instructions.

To determine if a facility is in a nonurbanized area, we propose that the most recently available U.S. Census Bureau list of Urbanized Areas (UA) be used. An area that is not in a UA would be considered a nonurbanized area. Information on whether an area is urbanized can be found at *http://factfinder.census.gov* or by contacting the appropriate CMS Regional Office (RO) at *http://www.cms.hhs.gov/RegionalOffices*.

To determine if a facility is in an area that has a current designation as an underserved or shortage area, the most current HRSA list of these designations would be used. Information on designation status, including the date of the most recent designation or update, is available on the HRSA Web site at *http://hpsafind.hrsa.gov/* and *http://muafind.hrsa.gov* or by contacting the appropriate CMS RO.

Health professional shortage area (HPSA) and MUA designations establish initial eligibility for Federal and State programs to improve access to health care services. They are based on established criteria (42 CFR part 5) to identify geographic areas or population groups with a shortage of primary health care services. HPSA designations are based primarily on the population to provider ratio in a defined service area. MUA designations utilize an Index of Medical Underserviced which calculates a score for each area based on a weighted combination of the ratio of primary medical care physicians per 1,000 population, infant mortality rate, percentage of the population with incomes below the poverty level, and percentage of the population age 65 or over.

(**Note:** HRSA has proposed a revision of the methodology used for determining HPSA and MUA designations. If necessary, this description of the designations will be updated in the final rule. Any change that HRSA makes to the methodology used to determine designations will not alter the requirements for the RHC program.)

Any of the following types of designations are acceptable for the purpose of RHC certification and compliance with this proposed requirement:

- Geographic Primary Care HPSAs (section 332(a)(1)(A) of the PHS Act)
- Population-group Primary Care HPSAs (section 332(a)(1)(B) of the PHS Act)
- MUAs (This does not include population group Medically Underserved Population designations) (Section 330(b)(3) of the PHS Act)
- Governor-designated and Secretary-certified shortage areas. (section 6213(c) of OBRA '89 (Pub. L. 101–239))

In section 302(a)(1)(A) of the Health Care Safety Amendments of 2002 (Pub. L. 107–251, October 26, 2002), the Congress amended section 332 of the PHS Act to create a new type of HPSA designation for FQHCs and RHCs referred to as an ''automatic'' HPSA designation. This type of designation is available to any RHC or FQHC irrespective of its physical location that utilizes sliding scale fees consistent with section 330 of the PHS Act for the purpose of National Health Service Corps eligibility. Facilities with these automatic HPSA designations are sometimes referred to as ''safety net facilities.'' However, we are proposing not to include the automatic HPSA designations as an eligible shortage area for purposes of Medicare qualifications as an RHC. Section 1861(aa)(2) of the Act specifically requires RHCs to be located in one of four specified designation types in which the Secretary has determined that there are

insufficient numbers of needed practitioners. Consequently, we would not recognize automatic HPSA designations for purposes of RHC certification or protecting a currently participating clinic from RHC decertification.

New and existing RHCs would have to be in a rural area that is currently designated as one of the four types of shortage areas listed previously. A designation is considered current for not more than 3 years after the date of the original designation or the date of the most recent update to the designation. An existing RHC that no longer meets would not be decertified based on the loss of its shortage area designation if: (1) A complete designation application has been received by HRSA before the end of the 3-year period since the shortage area designation date or most recent update; or (2) we have determined that the RHC is an essential provider. If either of these conditions is not met, the clinic would be terminated from participation in the Medicare program as an RHC 180 days after the date that the RHC no longer meets the location requirements, effective the last day of the month. States are encouraged to submit designation applications and updates to HRSA in a timely manner and may apply or reapply for a designation at any time.

2. Essential Provider Requirements

The RHC program was established for the purpose of improving and maintaining access to primary care for rural underserved communities. RHCs that apply to CMS for an exception to the location requirements must be able to show that they satisfy this program objective.

In accordance with section 1861(aa)(2) of the Act, an existing RHC may be considered essential to the delivery of primary care (a so-called ''essential provider'') if the care otherwise would be unavailable in the geographic area served by the clinic. The Secretary is directed by the Act to set the criteria by which ''essential provider'' status is to be determined. The Secretary has determined that an RHC may be considered an essential provider and be granted an exception to the location requirements if the clinic is no longer in a nonurbanized area or it is no longer in a currently designated shortage area, and it meets the criteria of an essential provider. An RHC that is neither in a rural area nor a designated area would not be considered an essential provider. Proposed criteria for essential provider status were published in the February 2000 proposed rule and have been revised based on comments that were received and other relevant information.

Under this authority, we are proposing the following requirements for essential provider status:

If an RHC is located in an area that has been classified as a UA by the U.S. Census Bureau, it would have to be in a level 4 or higher Rural Urban Commuting Area (RUCA) to assure that it is in a rural area. Under section 330A of the PHS Act, HRSA's Office of Rural Health Policy determines eligibility for its rural grant programs through the use of the RUCA code methodology. Under this methodology, any census tract that is in a RUCA level 4 or higher is determined to be a rural census tract. For the purposes of an exception to the RHC nonurbanized area location requirement, we would use the RUCA level 4 as the minimum level of rurality to meet this requirement.

Additionally, an RHC that is located in an area that has been classified as a UA by the U.S. Census Bureau would have to demonstrate that at least 51 percent of its patients reside in an adjacent nonurban area in order to be considered essential for the purposes of an exception to the location requirements. We prefer to give RHCs flexibility in establishing that at least 51 percent of their patients reside in an adjacent nonurban area; however, this could generally include the identification of the nonurban area(s) and a retrospective review of patient visits to determine residence, or other factors to support that the requirement has been met.

3. Location Exception Criteria

We are proposing to revise § 491.5 to specify that an RHC that meets the previously stated requirements may apply for an exception if it meets any one of the following criteria:

• *Sole Community Provider (proposed § 491.5(c)(1)):* The RHC is the only participating primary care provider that meets either of the following requirements:

++ The RHC is at least 25 miles from the nearest participating primary care provider; or

++ The RHC is at least 15 miles but less than 25 miles from the nearest participating primary care provider and can demonstrate that it is more than 30 minutes from the nearest primary care provider based on local topography, predictable weather conditions, or posted speed limits. (These criteria are based on the criteria established for sole community hospitals in § 412.92.) For purposes of this exception, a participating primary care provider would mean another RHC, FQHC, or primary care provider that is actively accepting and treating Medicare beneficiaries, Medicaid recipients, low-income patients, and the uninsured (regardless of their ability to pay).

• *Major Community Provider (proposed § 491.5 (c)(2)):* The RHC meets the following requirements:

++ Has a Medicare, Medicaid, low-income, and uninsured patient utilization rate greater than or equal to 51 percent, or a low-income patient utilization rate greater than or equal to 31 percent; and

++ Is actively accepting and treating a major share of Medicare, Medicaid, low-income and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers that are within 25 miles of the RHC.

• *Specialty Clinic: Obstetrics/Gynecology (Ob/Gyn) or Pediatrics (proposed § 491.5(c)(3)):* The RHC meets the following requirements:

++ Exclusively provides ob/gyn or pediatric health services (as applicable).

++ Is the sole or major source of ob/gyn or pediatrics for Medicare (where applicable), Medicaid, and uninsured patients (regardless of their ability to pay) and is either of the following:

—At least 25 miles from the nearest participating provider of ob/gyn or pediatric services.

—At least 15 miles but less than 25 miles from the nearest participating provider of ob/gyn or pediatric services, and can demonstrate that it is more than 30 minutes from the nearest participating primary care provider providing these services based on local topography, predictable weather conditions, or posted speed limits.

++ Is actively accepting and treating Medicare, Medicaid, low-income, and uninsured patients.

++ Has a Medicare, Medicaid, low-income patient and uninsured utilization rate greater than or equal to 31 percent.

++ Provides ob/gyn (including prenatal care) or pediatric services onsite to clinic patients.

• *Extremely Rural Community Provider (Proposed § 491.5(c)(4)):* The RHC meets the following requirements:

++ Is actively accepting and treating Medicare, Medicaid, low-income, and uninsured patients (regardless of their ability to pay).

++ Is located in a frontier county (a county with 6 or less persons per square mile) or in census tract or zip code with a RUCA code 10.

In the December 2003 final rule, we included RHC's that are mental health

specialty clinics as an acceptable category for an exception to the location requirements. However, section 1861(aa)(2)(iv) of the Act prohibits RHC status from being applied to clinics which are ''primarily for the care and treatment of mental diseases.'' We interpret ''primarily'' to mean that mental health services provided by the RHC cannot constitute more than 50 percent of the total services provided by the RHC.

In order to assure that the regulation and statue are consistent, we are asking for comments on—(1) whether it is appropriate to allow an exception to the location requirements for RHCs based on the provision of mental health services in light of the fact that RHC status cannot be granted to a facility providing more than 50 percent of its total services in mental health; and (2) if so, what should be the minimum level of mental health services provided in order to qualify for an exception. This would apply only to existing an RHC that no longer meet the location requirements, either because it is no longer in a non-urbanized area, or because it is no longer designated by HRSA as an underserved or shortage area. Existing RHCs that are in compliance with the location requirements may continue to provide mental health services as long as the mental health services provided do not exceed 50 percent of the total clinic services.

4. Process for Essential Provider Status and Timeline

An RHC that is located in (a) an area that has not been designated or its designation was not been updated for more than 3 years, or (b) an urbanized area that is defined by the Census Bureau, would have 90 calendar days from the effective date of the final rule to apply to CMS RO for an exception to the location requirement. The RHC may continue to operate as an RHC for an additional 90 days, for a total of 180 calendar days after the end of the 3-year period. To assist with the cost reporting and payment reconciliation process, decertification would be effective on the last day of the month in which the 180-day limit was met.

An RHC would have 180 days after the date that it does not meet the location requirements to continue operating as an RHC. We expect that most RHCs that do not meet the location requirements would want to know as soon as possible if they would receive an exception to the location requirements and would want as much time as possible to make other arrangement for the provision of services after the 180 days, so it is in the interest of the RHC to apply for an exception to the location requirements as soon as possible.

An RHC which is located in an area which has been found by HRSA to no longer qualify for one of the 4 types of eligible designations would have 90 calendar days from the date HRSA determined that the area no longer qualified for one of the eligible designations to apply to CMS RO for an exception from decertification. This would include designations that are proposed for withdrawal, as well as areas whose designations type has changed to one that does not meet the RHC criteria.

For example, if HRSA determines on April 1, 2009, that the area no longer qualifies for one of the designations required for RHC purposes, the RHC would have until June 30, 2009 to submit an application to the appropriate RO for a location exception, and would be protected until September 30, 2009 from decertification based on not meeting the location requirements.

An RHC which is located in an area whose designation has not been updated in a timely manner and which does not apply for a location exception may continue to operate as an RHC for 180 calendar days after the 3 years from the date of the last designation, effective the last day of the month.

An RHC may be decertified 180 days after the 3-year date of the area's designation if it does not provide a complete application for a location exception within 90 days from the date it no longer meets the location requirements, or if the application for a location exception is not approved. In rare circumstances, the RO may request an extension from the CMS Central Office if it has not been possible to process the location exception request before the RHC would be decertified.

For example, (see accompanying sample timeline) if an area was designated (either a new designation or an update) on January 2, 2006 (#1 on sample timeline), the designation would be considered valid for RHC purposes for 3 years, which would be January 2, 2009 (#2). If an application to update the designation is submitted to HRSA by January 2, 2009 (#3), the RHC would be protected from decertification while the HPSA application is under review (#3.1). If the area qualifies as a HPSA and is updated (#3.2), then no further action would be needed for purposes of the RHC designation for 3 years from the date of the designation update (#3.3). If a HPSA application is submitted by January 2, 2009 (#3), but is determined to not qualify as a HPSA (#3.1.1), then the RHC would have 90 days from the date of that determination to submit an application for an exception (#3.1.2).

If an application to update the designation is not submitted to HRSA by January 2, 2009 (#4), the RHC would have until April 3, 2009 (#4.1), to submit an application for a location exception. If the RHC does not submit an application for a location exception to CMS by April 3, 2009 (#4.2), it would be decertified on July 31, 2009 (#4.3). (Decertification is effective the final day of the month.)

An RHC that submits an application for a location exception would be protected from decertification while the application is under review (#5). If the application is approved (#5.1), then no further action would be needed for purposes of the RHC recertification for 3 years from the date of the exception (#5.1.1). If the application is not approved (#5.2), the RHC would be decertified 90 days from the date of notification that the application was not approved (#5.2.1).

The process to appeal a denial of certification is described in § 498.3(b)(5). For the purpose of an appeal, RHCs and FQHCs are considered suppliers, not providers.

In the December 24, 2003 final rule, we stated that an RHC would have 120 days from the date of notification that it was no longer in a designated area and therefore not compliant with the RHC requirements to submit an application to update its MUA or HPSA designation. Although HRSA regulations do not preclude RHCs from submitting a designation application, it is usually the State not the RHC that submits the designation application. The State should not wait until a designation is more than 3 years old to prepare and submit an update for RHC purposes. As noted previously, an existing RHC is protected from decertification based on its designation status as long as an application has been submitted for an updated designation. We encourage RHC to work with the applicable State Primary Care Office to assure that any necessary information is provided to HRSA in a timely manner. A list of the State Primary Care Offices is available online at *http://hrsa.gov/grants* and then by selecting ''HRSA Grantees by Program or State'' and then by selecting ''State Primary Care Offices'', or by contacting the State's Department of Health.

An RHC that chooses to apply for an exception to the location requirements would send its application with the necessary documentation to the appropriate RO. An RHC that applied for an exception would not be

disqualified as an RHC based on not meeting the location requirements while its application is under review. If approved, the exception would be for a period of 3 years. Every 3 years, an RHC may reapply for an exception to the location requirements to continue its RHC eligibility.

Some provider-based RHCs that do not meet the location requirements and do not qualify for an exception may want to continue to operate as another type of Medicare provider. In some cases, these entities will need to go through the standard Medicare application process, which includes an application and, for entities wishing to enroll as a ''provider of services'' under 1861(u), a state survey. We have been informed that the waiting time for a state survey can be several months, so we are proposing that provider-based RHCs that do not meet the location requirements and do not qualify for an exception and have submitted an application to CMS to be another type of Medicare provider that requires a State survey for certification may receive an additional 120-day extension of their status as an RHCs while their application is being processed.

We propose to revise § 491.2 to redefine ''shortage areas'' as geographic and population group HPSAs, MUAs, and areas designated by the Governor of the State and certified by the Secretary.

We propose to amend § 491.3 as follows by adding paragraphs (a)(1) through (a)(3) to specify general certification requirements, and (b)(1) to specify permanent and mobile unit requirements.

We propose to amend § 491.5 as follows:

- Adding paragraphs (a)(1) through (a)(3) to specify the location requirements for RHCs and FQHCs.
- Adding paragraph (a)(4) to specify when a clinic would be terminated from the RHC program.
- Adding paragraphs (a)(5) and (a)(6) to specify the requirements for being considered an essential provider.
- Adding paragraph (a)(7) to specify the time period for a clinic's essential provider status.
- Adding paragraph (a)(8) to specify the time period that a decertified RHC may continue to operate.
- Adding paragraph (a)(9) to specify that conditions for an extension of RHC status when the location requirements are not met and the clinic does not qualify for an exception.
- Adding paragraphs (b)(1) through (b)(4) to specify the criteria for an exception from the location requirements.
- Adding paragraphs (c)(1) and (c)(2) to specify the conditions for termination.
- Adding paragraphs (d)(1) through (d)(8) to set forth the circumstances and timeline for submitting a request for an exception to the location requirements.

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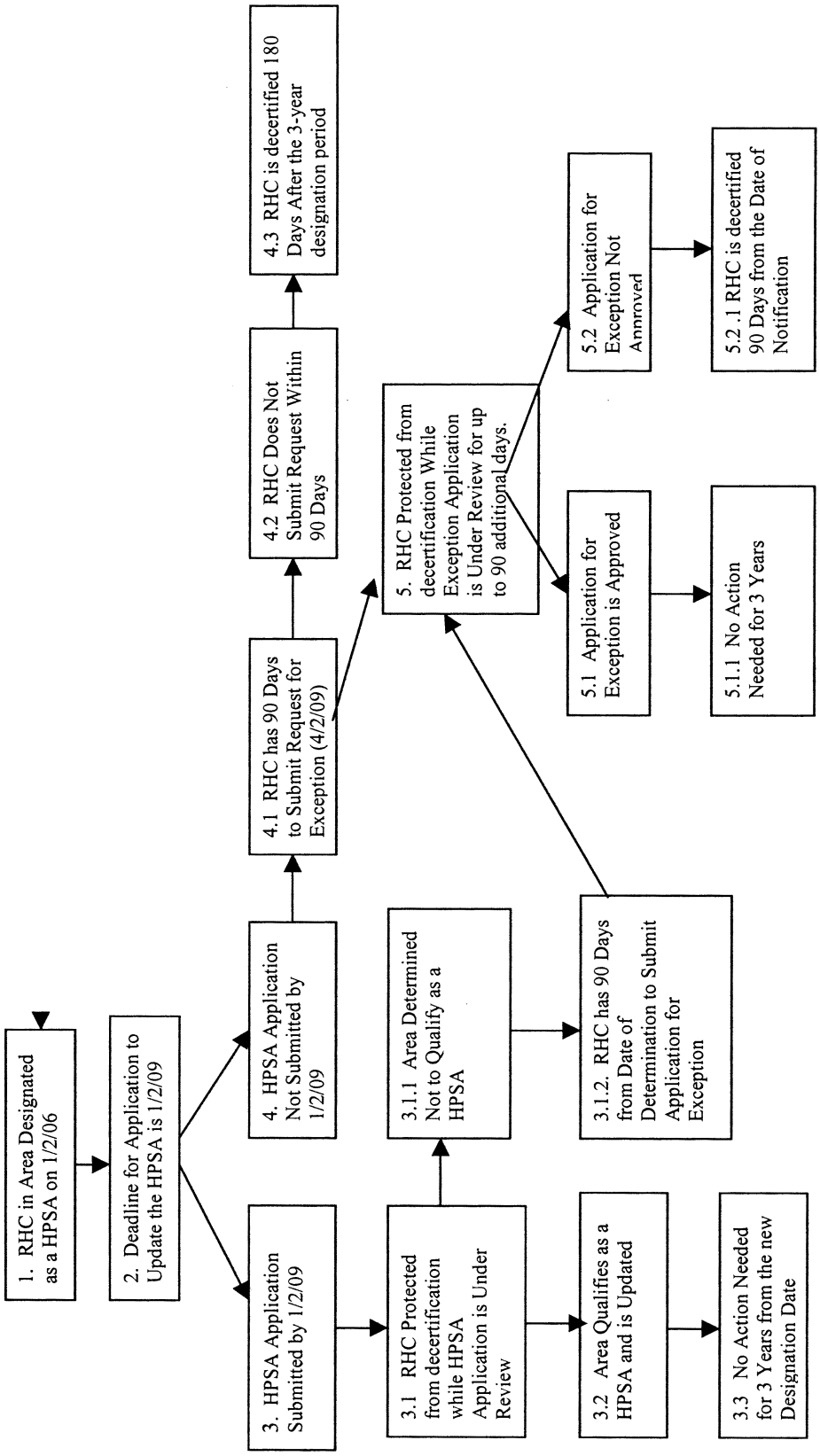
Sample Timeline



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B. Staffing Requirements, Waivers, and Contracts

1. Staffing Requirements

One of the goals of the RHC program is to encourage the use of nonphysician practitioners to provide quality health care in rural areas. We propose to amend § 491.8(a)(6) to conform with section 6213(a)(3) of OBRA '89 (Pub. L. 101–239) which requires that an NP, PA, or CNM be available to furnish patient care at least 50 percent of the time the RHC operates. An RHC that opens its premises solely to address administrative matters or to allow patients shelter from inclement weather would not be considered to be in operation as an RHC during that period.

2. Temporary Staffing Waivers

We propose to amend § 491.8(d) to conform with section 1861(aa)(7) of the Act, which authorizes us to grant a 1-year waiver of staffing requirements for nonphysician primary care providers (NPs, PAs, or CNMs) upon request from the RHC. The requesting RHC would have to demonstrate that it made a good faith effort to recruit and retain an adequate number of nonphysician primary care providers, and that it has been unable in the 90-day period prior to the request to hire one of these providers to meet the staffing requirement. This could include activities such as advertising in a newspaper, advertising in a professional journal, conducting outreach to an NP, PA, or CNM school, or other activities that would demonstrate a good faith effort to recruit and retain a nonphysician primary care provider. In accordance with section 1861(aa)(7)(B) of the Act, this waiver would be available only to existing RHCs that meet the nonphysician primary care requirement before seeking the waiver.

Section 1861(aa)(7) of the Act also specifies that an additional waiver cannot be granted until a minimum of 6 months has passed since the expiration of the previous waiver.

We are proposing that an RHC that has not complied with staffing requirements for one or more nonphysician primary care providers and has not submitted a request for a waiver of this requirement would be decertified from the RHC program. The decertification would be mandatory, since the noncompliant facility would fail to meet the statutory definition of an RHC. An RHC that has submitted a waiver request would not be decertified based on this requirement while its request was under review. A waiver would be deemed granted after 60 days, unless written notification is provided that the request has been denied. An RHC that is decertified from the RHC program due to failure to meet the staffing requirements would no longer be eligible to operate as an RHC. However, the RHC could apply to become a physician-directed clinic, group practice, or a group of individual practitioners who would then bill Medicare using the Part B fee-for-service system.

3. Contractual Arrangements

Due to the difficulty in recruiting and retaining physicians in rural areas, RHCs have had the option of hiring physicians either as RHC employees or as contractors. However, in order to promote stability and continuity of care, the Rural Health Clinic Services Act of 1977 required RHCs to ''employ a physician assistant or nurse practitioner'' (section 1861(aa)(2)(iii) of the Act). We note that the term ''employee'' is defined in section 3121(d)(2) of the Internal Revenue Code of 1986 and is usually evidence by the employer's provision of a W–2 form to the employee. Our current regulations at § 405.2468(b)(1) state that '' * * * (RHCs are not paid for services furnished by contracted individuals other than physicians).''

In the more than 30 years since this legislation was enacted, the health care environment has changed dramatically, and RHCs have requested that they be allowed to enter into contractual agreements with PAs and NPs as well as physicians. To provide RHCs with greater flexibility in meeting their staffing requirements, we propose to revise § 405.2468(b)(1) by removing the parenthetical ''RHCs are not paid for services furnished by contracted individuals other than physicians.'' Also, we propose to revise § 491.8(a)(3) to state that nonphysician practitioners may furnish services under contract to an RHC within the statutory limits.

RHCs would still be required, under section 1861(aa)(2)(iii) of the Act, to employ a PA or NP. However, as long as there is at least one PA or NP employed at all times (subject to the waiver provision set forth at section 1861(aa)(7) of the Act), an RHC would be free to enter into employment contracts with other PAs, NPs, or other nonphysician staff.

FQHCs already have the option to contract with PAs and NPs. Authority to allow contracting for clinical services is provided for in the PHS Act. The authority to allow Medicare participating FQHCs to contract with any necessary health professional for the purpose of treating their patients is further clarified by section 5114 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) which amended section 1842(b)(6) of the Act to require consolidated billing of contracted professional services by adding new subsection (H) with the following language: ''in the case of services described in section 1861(aa)(3) of the Act that are furnished by a health care professional under contract with a Federally qualified health center, payment shall be made to the center.'' Similar language regarding contracted medical professionals was also added to section 1861(aa)(3) of the Act. FQHCs and RHCs also have authority to claim the costs of such contracted practitioners' services on the Medicare cost report to receive Medicare payment.

A practitioner providing services under contract to the RHC or FQHC should have a signed contract that includes his or her responsibilities and requirements. All practitioners should be familiar with the clinic or center's policies and procedures, and comply with the staffing requirements in § 491.8. Practitioners should be employed or contracted to the RHC in a manner that enhances continuity and quality of care.

We propose to remove the parenthetical statement at § 405.2468(b)(1) which states that RHCs are not paid for services furnished by contracted individuals other than physicians. We also propose to revise § 491.8(a)(3) to state that nonphysician practitioners may furnish services under contract to an RHC.

C. Payment Issues

1. Payment Methodology for RHCs and FQHCs

Payment to RHCs and FQHCs for covered services furnished to Medicare beneficiaries is made on the basis of an all-inclusive rate per visit, subject to a payment limit. The Medicare Administrative Contractor (MAC) or FI determines the all-inclusive rate in accordance with this subpart and instructions issued by CMS.

With the exception of services provided under Medicare Advantage plans to RHCs and FQHCs, the statutory payment requirements for RHC and FQHC services are set forth at section 1833(a)(3) of the Act, (as amended by the MMA), which states that RHCs and FQHCs are paid reasonable costs ''* * * less the amount a provider may charge as described in clause of section 1866(a)(2)(A), but in no case may the payment exceed 80 percent of such costs[.]'' The beneficiary is responsible for the Medicare Part B deductible

(except for services provided in FQHCs, where there is no Part B deductible) and coinsurance amounts. Section 1866(a)(2)(A)(ii) of the Act and implementing regulations at § 405.2410(b) establish beneficiary coinsurance at an amount not to exceed 20 percent of the clinic's reasonable charges for covered services.

Section 237(c) of the MMA which pertains to cost sharing permitted under MA organizations, revised section 1857(e) of the Act. These changes were addressed in § 405.2469 as part of the CY 2006 Physician Fee Schedule final rule with comment period (70 FR 70116).

In general, the statutory payment methodology requires that except for services provided under MA plans to FQHCs in accordance with section 1833(a)(3)(B) of the Act, RHCs and FQHCs subtract beneficiary coinsurance and deductible amounts, as applicable (based on reasonable charges) from reasonable costs to determine the Medicare payment. The statute further stipulates that Medicare reimbursement may not exceed 80 percent of reasonable costs.

Until now, Medicare has been paying RHCs and FQHCs 80 percent of the facility's reasonable costs, regardless of deductible and coinsurance amounts billed to Medicare beneficiaries. This allowed RHCs and FQHCs to receive, in some instances, payment in excess of 100 percent of reasonable costs.

Therefore, to conform existing regulations to the statutory payment methodology described above, we propose to revise § 405.2410 and § 405.2466(b)(1)(iii) by stipulating that, except for services provided under MA plans to FQHCs, Medicare payment is equal to reasonable costs less aggregate coinsurance and deductible amounts billed, but in no case may total Medicare payment exceed 80 percent of reasonable costs.

Note: Payment for the outpatient treatment of mental, psychoneurotic, or personality disorders is subject to the limitations on payment in § 410.155

2. Exceptions to the Per Visit Payment Limit

Prior to the BBA, the payment methodology for an RHC depended on whether it was ''provider-based'' or ''independent.'' Payment to provider-based RHCs for services furnished to Medicare beneficiaries was made on a reasonable cost basis by the provider's FI in accordance with our regulations at 42 CFR part 413. Payment to independent RHCs for services furnished to Medicare beneficiaries was made on the basis of a uniform all-inclusive rate payment methodology in accordance with 42 CFR part 405, subpart X. Payment to independent RHCs also was subject to a maximum payment per visit as set forth in section 1833(f) of the Act.

Section 4205(a) of the BBA amended section 1833(f) of the Act. Under the BBA, the independent RHC all-inclusive payment methodology and payment limit were applied to provider-based RHCs. This BBA provision also provided an exception to the RHC payment limit for those RHCs based in small, rural hospitals to help them remain financially viable.

Section 224 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) enacted on December 21, 2000, expanded to RHCs based in small, urban hospitals the eligibility criteria for receiving an exception to the RHC payment limit, effective July 1, 2001. This was implemented through a program memorandum on December 6, 2001.

If an RHC is an integral and subordinate part of a hospital, it can receive an exception to the per visit payment limit if the hospital has fewer than 50 beds as determined by using one of the following methods:

- The determination of the number of beds at § 412.105(b); or
- The hospital's average daily patient census count of those beds described in § 412.105(b), and the hospital meets all of the following conditions:

++ It is a sole community hospital as determined in accordance with § 412.92 or § 412.109(a).

++ It is located in a level 9 or 10 RUCA.

++ It has an average daily patient census that does not exceed 40.

The December 24, 2003 final RHC rule used the 1993 Urban Influence Codes (UICs), then a 9-category measure developed by the U.S. Department of Agriculture (USDA), to identify hospitals which are located in sparsely populated rural areas. Hospitals with a level 8 or 9-level UIC and which have an average daily census of less than 50 patients would qualify for an exception to the RHC per visit payment limit. The USDA has since changed the UICs to a 12-category measure, with levels 9 through 12 comparable to the 1993 levels 8 and 9.

The UICs are a county-level measurement. Since many counties encompass large geographical areas with significant variations in population density, demographics, economics, and health care services, the UICs do not always provide an accurate assessment of a local area's degree of rurality.

The RUCA system is another method for identifying rural areas. RUCA codes classify U.S. census tracts using measures of population density, urbanization, and daily commuting. This classification uses 10 numbers with subdivisions to reflect commuting flows.

RUCAs are used by CMS for purposes of determining rurality in the hospital and ambulance payment systems. To target the needs of rural populations more accurately and to be consistent with other CMS programs, we propose to utilize the RUCA methodology instead of the UIC methodology. We also propose that RUCA codes 9 and 10 be used for the purpose of approving an exception to the per visit payment limit.

We propose to amend § 405.2462 to provide payment to all RHCs and FQHCs on the basis of an all-inclusive rate per visit, subject to the per-visit payment limit. For a hospital-based RHC that is the primary source of health care in its rural community as defined at § 412.92(a) or § 412.109(a), we propose to utilize the hospital's average daily census rather than bed count in determining whether RHC services are subject to the per-visit payment limit. We also propose to utilize RUCAs 9 and 10 to determine eligibility for an exception to the per visit payment limit.

3. Commingling

Commingling refers to the sharing of RHC space, staff (employees or contractors), supplies, records, and other resources with an onsite Medicare Part B or Medicaid fee-for-service practice operated by the same RHC physician(s) or nonphysician practitioner(s) or both. Commingling is prohibited when it results in duplicate Medicare or Medicaid reimbursement, either due to the inability of the RHC to distinguish its actual costs from those that are reimbursed on a fee-for-service basis, or due to other reasons.

An RHC and a Medicare fee-for-service practice may not operate simultaneously in order to prohibit these shared practices from selecting patient encounters for enhanced Medicare Part B billing.

However, an RHC that is part of a multipurpose clinic may house other entities (such as private medical practices, x-ray and lab clinics, dental clinics, emergency room) in the non-RHC space. The entities occupying the non-RHC space may bill the assigned Medicare Administrative Contractor (MAC), Fiscal Intermediary (FI), or carrier as appropriate; authority is delegated to the MAC, FI, or carrier to

determine acceptable accounting methods for allocation of staff costs between the RHC and other entities to be used in documenting allocation of costs. Since in a multipurpose clinic the RHC may share some resources in common with the non-RHC entity (for example, waiting room or receptionist), the RHC must maintain accurate records to assure that the RHC costs that it claims for Medicare reimbursement are only for the staff, space, or other resources that are used for RHC purposes. Any shared staff, space, or other resources must be allocated appropriately between the RHC and non-RHC usage to avoid duplicate reimbursement.

This commingling policy does not prohibit a hospital-based RHC from sharing its health care practitioners with the hospital emergency department in an emergency, or prohibit an RHC physician from providing on-call services for an emergency room, as long as the RHC continues to meet the RHC conditions for certification (CfCs) in the absence of the practitioner(s) and the RHC is able to allocate appropriately the practitioner's salary between RHC and non-RHC time.

Facilities are encouraged to work with their MAC, FI, or carrier and RO in determining permissible resource-sharing situations and proper cost reporting methods.

4. Payment for Services to Hospital Patients

The hospital inpatient bundling provision was enacted on April 20, 1983 in section 602(e)(3) of the Social Security Act Amendments of 1983 (Pub. L. 98–21), by adding paragraph (a)(14) to section 1862 of the Act. The hospital outpatient bundling provision was enacted in section 9343(c) of OBRA '86, Public Law 99–509. Taken together, these two provisions require bundling of the costs for all nonprofessional services furnished to hospital patients. Consequently, section 1862(a)(14) of the Act now requires hospitals and CAHs to bundle all costs, other than those for the professional services specified in the statute.

Only professionals exempt from the hospital bundling provisions are permitted to bill for services furnished to hospital patients. RHCs and FQHCs cannot bill for services furnished by RHC practitioners to hospital patients because RHC and FQHC services are not exempt from the hospital bundling provisions.

Accordingly, any costs incurred by an RHC or FQHC associated with the provision of services to hospital patients must be excluded from RHC or FQHC allowable costs on their Medicare cost report. However, a practitioner who provides services in an RHC or FQHC may, in some cases, also have a private practice and be enrolled and qualified to bill Medicare under that practice as a Part B practitioner. In these situations, the practitioner may be able to bill Medicare Part B under their private practice for covered services provided to hospital patients.

Section 1862(a)(14) of the Act places restrictions on the payment for services furnished to hospital and CAH patients. We propose to revise § 405.2411(b) and (c) to specify that RHC services are covered when furnished in an RHC setting or other outpatient setting, but are not covered when furnished in a hospital or CAH.

5. Payment for Services to Skilled Nursing Facility (SNF) Patients

Section 4432(b) of the BBA amended the statute to add a consolidated billing provision for SNFs in section 1862(a)(18) of the Act. Similar to the hospital bundling provision in section 1862(a)(14) of the Act, this provision bundled all Part B services furnished to SNF residents during a covered Part A stay into the SNF Prospective Payment System (PPS) rates, except those services specifically excluded under statute. RHC services were not among the excluded services. Although the Congress excluded physician services and several other services from the SNF bundle of services, RHC and FQHC services were not among the services on the excluded under section 1888(e)(2)(A)(ii) of the Act. Consequently, through program instructions to Medicare contractors (PM A–99–8, March 1999), we announced that under the statute, RHC and FQHC services furnished to SNF residents were subject to the SNF consolidated billing provision and could not be billed to Medicare by the RHC or FQHC.

However, section 410 of the MMA amended section 1888(e)(2)(A) of the Act by adding a new paragraph (iv) to exclude RHC and FQHC services from the SNF consolidated billing provision. This MMA change was effective for services furnished on or after January 1, 2005. In accordance with this section of the MMA, services included within the scope of RHC and FQHC services described at section 1888(e)(2)(A)(ii) of the Act are excluded from the SNF consolidated billing provision. These services are limited to physician, PA, NP, CP, and CNM services. Only this subset of RHC and FQHC services may be covered and paid through the RHC and FQHC benefit when furnished to RHC and FQHC patients in a Medicare Part A covered SNF stay. Payment for this subset of services is made in the usual manner under the RHC and FQHC all-inclusive payment methodology. All services other than physician, PA, NP, CP, and CNM services that an RHC or an FQHC may furnish to a patient in a Medicare covered Part A SNF stay are subject to the SNF consolidated billing provision. This means any costs associated with these other services are excluded from coverage and payment under the RHC and FQHC benefit when furnished to a Part A SNF patient.

We propose to require in § 405.2411(b) and (c) that payment for RHC services furnished to patients at the RHC, at the patient's place of residence, or at another facility other than a hospital or CAH, be made to the RHC. As a result of the provisions in section 1862(a)(14) of the Act, RHCs and FQHCs cannot bill for RHC or FQHC services furnished by their practitioners to hospital or CAH inpatients.

6. Payment for Certain Physician Assistant Services

Sections 4511 and 4512 of the BBA removed the restrictions on the types of areas and settings in which the Medicare Part B program pays for the professional services of NPs, CNSs, and PAs. This provision also expanded the professional services benefits for NPs and CNSs by authorizing them to bill the program directly for their services when furnished in any area or setting. However, these BBA provisions maintained the current policy that payment for PA services can be made only to the PA's employer regardless of whether the PA is employed directly or is serving as an independent contractor.

Section 4205(d)(3)(B) of the BBA amended section 1842(b)(6)(C) of the Act to provide that payment for PA services may be made directly to a PA under certain circumstances. This provision permits Medicare to directly pay a PA who is the owner of an RHC, as described in section 1861(aa)(2) of the Act, for a continuous period beginning before the date of the enactment of the BBA and ending on the date the Secretary determines the RHC no longer meets the requirements of section 1861(aa)(2) of the Act, for services furnished before January 1, 2003.

Section 222 of the BIPA amended section 1842(b)(6)(C) of the Act, which permits PAs who owned RHCs and subsequently lost RHC status to receive direct Medicare payment for their services, effective December 21, 2000. This BIPA provision eliminated the January 1, 2003 sunset date. We propose

to revise § 410.150(h)(15) and add § 410.150(b)(20) to allow PAs to receive direct Medicare payment for services provided by the RHC, as long as the RHC continues to meet the requirements of section 1861(aa)(2) of the Act.

7. Screening Mammography

In June 2000 we released Program Memorandum A–00–30, which stated that preventive physician and nonphysician services, such as screening mammography, were covered when performed in an RHC/FQHC to the same extent as other RHC/FQHC services. We propose to revise § 405.2448 by removing paragraph (d), which states that screening mammography is not considered a covered FQHC service.

8. Payment for High Cost Drugs

RHCs are reimbursed based on an all-inclusive payment methodology, subject to an upper payment limit, which includes the cost of drugs provided incident to a patient visit. We are aware that many RHCs would like to provide services such as outpatient cancer treatments to their patients, and that the patients would benefit from this service by not having to travel greater distances to receive treatment elsewhere. However, because drugs are included in the all-inclusive rate per visit, it may not be financially viable for an RHC to provide treatments that require high cost drugs for their patients.

We recognize the dilemma that RHCs may face in deciding whether to provide certain treatments in the RHC that would benefit their patients but may put their financial viability at risk. Therefore, we are soliciting comments on this situation and possible solutions that can be addressed through regulation or program guidance. Any possible solution would need to take into account our legislative authority, which does not generally allow reimbursement to RHCs for drugs, our policy on commingling, and the need for administrative accountability.

D. Health and Safety, and Quality

1. Quality Assessment and Performance Improvement Program (QAPI)

Currently, each RHC is required to evaluate its total program annually. The evaluation must include reviewing the utilization of the clinic's services using a representative sample of both active and closed clinical records, as well as reviewing the clinic's health care policies. The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and if any changes are needed. The clinic's staff considers the findings of the evaluation and takes the necessary corrective action. These requirements focus on the meeting and documentation of the clinic's evaluation of its quality care and do not account for the outcome of these activities.

Section 4205(b) of the BBA amended section 1861(aa)(2)(I) of the Act to authorize us to require that an RHC have a quality assessment and performance improvement program (QAPI). Therefore, RHCs are required by statute to have a QAPI program and it is a requirement for certification as an RHC. Upon an initial or subsequent survey, an RHC would be required to develop a plan of correction where a viable QAPI program is not in effect.

A QAPI program enables the organization to systematically review its operating systems and processes of care to identify and implement opportunities for improvement.

Some RHCs have already incorporated a QAPI program into normal RHC operating activities. For those which are starting to develop an appropriate QAPI program, guidance and examples of QAPI-related activities are available from professional and governmental organizations, including some State offices of rural health.

HHS previously has contracted with the National Association of RHCs (*http://www.narhc.org*) to develop technical assistance materials which provide guidance for RHCs in complying with QAPI requirements. These and other materials are available through HRSA's Office of Rural Health Policy (*http://www.ruralhealth.hrsa.gov*). Information is also available from the Rural Assistance Center (*http://www.raconline.org*), the National Rural Health Association (*http://www.nrharural.org*), and the Rural Policy Research Center (*http://www.rupri.org*). As it develops its QAPI program, an RHC may find additional guidance through the information contained in the Institute of Medicine report, ''Quality Through Collaboration: The Future of Rural Health Care'', as well as that contained at the database and Web site sponsored by the agency for Healthcare Research and Quality, the National Quality Measures Clearinghouse (*http://www.qualitymeasures.ahrq.gov/*). RHCs are encouraged to take advantage of the resources available.

We would deem an RHC that chose to utilize a QAPI model program provided by the Department (or other on-line resources mentioned in this regulation) to have met the QAPI CfC, provided that the model program chosen was one that was in compliance with the substantive provisions of § 491.11.

We propose to revise § 491.11 to set forth explicit requirements for a QAPI program. An RHC would set its own priorities for performance improvement based on the prevalence and severity of identified problems. The QAPI program would contain three standards that would address: (1) Program components; (2) program activities; and (3) program responsibilities.

The first standard, § 491.11(a), would require that an RHC use objective measures to evaluate organizational processes, functions and services and the use of clinic services, including at least the number of patients served and the volume of services.

The second standard, § 491.11(b), would require RHCs to adopt or develop performance measures that reflected processes of care and RHC operation and were shown to be predictive of desired patient outcomes or were the outcomes themselves. The RHC would have to use the measures to analyze and track its performance. The RHC would set priorities for performance improvement, considering high-volume, high-risk services, the care of acute and chronic conditions, patient safety, coordination of care, convenience and timeliness of available services or grievances and complaints. Also, the RHC would have to conduct distinct improvement projects and maintain records on its QAPI program for each of the areas listed under the standard in § 491.11(a). Additionally, a project to develop and implement an information technology (IT) system explicitly designed to improve patient safety and quality of care would be considered as meeting the requirement for a QAPI project under this section. We are proposing this IT provision because we believe that it is critically important that RHCs identify opportunities to improve and expand the use of information technology to prevent medical errors and improve 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 IT (such as computerized patient records). We encourage RHCs, as they assess their organizational processes, functions, and services, to identify opportunities and make use of information technologies. We believe that the effective use of IT systems could prove invaluable to improving the quality and safety of patient care over time. We would allow RHCs to receive QAPI recognition for undertaking programs of investment and development of IT systems that are

designed to result in improvements in patient safety and quality of care as an alternative to other performance improvement projects (see § 491.11(b)(4)). In recognition of the time and resources required to implement these IT programs, we would not require associated activities to have a demonstrable benefit in the initial stages, but would expect that the quality improvement goals and the associated achievements would be incorporated in the plans for these programs.

The third proposed standard, § 491.11(c), would require that the RHCs professional staff, administrative officials, and governing body (if applicable) ensure that there is an effective QAPI plan that addresses identified priorities.

2. Infection Control

While the physical plant and environment standard in § 491.6(a)(3) requires that RHCs and FQHCs keep the premises clean and orderly, there is no current Medicare standard addressing infection control in RHCs and FQHCs. We believe that RHCs and FQHCs should be required to have infection control guidelines and an implementation plan. The value of infection control measures in reducing infectious and communicable diseases long has been recognized, and we realize that a large number of clinics and centers may be implementing some aspects of an infection control program. However, because of the real and potential hazards which infectious and communicable diseases present, we believe that it would be prudent to add a formal standard requiring adherence to infection control guidelines that have been recognized by industry standards and regulatory bodies as being appropriate for facilities such as RHCs and FQHCs. The Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA), in their October 1999 Consensus Panel Report, stated that infection prevention and control issues are important throughout a continuum of care, including physicians' offices, clinics, ambulatory surgical centers, and in individuals' homes through home health agencies. Likewise, a Centers for Disease Control (CDC) article, entitled ''Health-Care Quality Promotion, through Infection Prevention: Beyond 2000''; Vol. 7, No. 2, March–April 2001, by Julie Louise Gerberding, reported that the urgent need for enhanced infection prevention programs in nonhospital settings has been acknowledged for more than a decade. However, programs designed to effectively address this need have been slow to evolve. One contributing factor offered in the article was a lack of regulatory and accreditation standards to ensure that truly effective program components are in place.

We agree with the CDC's findings as well as with the intent of the article, and are proposing that the new infection control standard place accountability on RHCs and FQHCs to prevent and control infectious and communicable diseases, and to take actions that result in improvements to infection control practices.

We are proposing to add, under § 491.6, a new paragraph (d) that would require RHCs and FQHCs to have infection control guidelines and an implementation plan. Model guidelines are available from various professional organizations, and RHCs and FQHCs would have flexibility in determining how best to meet these objectives. For example, RHCs and FQHCs would determine how much staff training in infection control would be necessary, the method of oversight, and the appropriate level of documentation that would be required. However, we do expect that RHC and FQHC staff engaged in direct patient care would follow current accepted standards of infection control practice (for example, wearing gloves when handling blood or blood products, and following hand hygiene guidelines). We believe that if a clinic or center currently complies with the infection control standards of the industry for outpatient health care facilities, then they would most likely meet or exceed this proposed standard. The infection control activities should be an integral part of the RHCs or FQHCs overall QAPI program and the FQHCs quality improvement program as also required by section 330(k)(3)(C) of the PHS Act, and should be addressed in these programs on an ongoing basis.

3. Hours of Operation

a. Posting of Hours

RHCs and FQHCs have varying hours and days of operation based on staff and anticipated patient load. Beneficiaries in rural areas often travel long distances to obtain services. Therefore, we are proposing to require under § 491.6(e) that an RHC or FQHC must post at or near the entrance to the facility a sign that states the days of the week and hours when RHC or FQHC services are furnished. This information would have to be displayed in a manner so that it can be viewed easily by persons who have vision problems and who are in wheelchairs.

b. Use of the RHC Facility

Section 491.8(a)(6) states that a RHC must have a physician, NP, PA, CNM, CSW, or CP available to furnish patient care services at all times the RHC operates, and that an NP, PA, or CNM must be available to furnish patient care services at least 50 percent of the time the RHC operates.

To provide RHCs with flexibility to allow access patients to enter the RHC for purposes other than patient care while complying with the requirements of § 491.8(a)(6), we are clarifying that RHCs may allow patients to enter the waiting room or other areas not utilized for patient care when the premises are opened solely to address administrative matters, or to allow patients entry into the building to get out of inclement weather. The RHC would not be considered ''in operation'' as an RHC during these periods. No health care services would be provided until a physician, NP, PA, CNM, CSW, or CP was present to provide such services. RHCs that choose to exercise this flexibility should post the hours they offer administrative services only versus the hours they offer RHC health care services. The signage which would be required by § 491.6(e) should clearly delineate the times the NP, PA, CNM, CSW, CP, or physician was present and the RHC would be in operation and providing health care services. If State law does not allow access to the RHC premises when the RHC is not in operation as an RHC, the facility must adhere to State law.

4. Emergency Services and Training

We propose to revise § 491.9(c)(3) to reflect current industry standards and procedures for first responses to common life-threatening injuries and acute illnesses. We would expect that clinical personnel responding to emergencies would assess and stabilize sick or injured persons and administer emergency medical treatment while waiting for emergency transport to arrive or until such time that the patient could receive an advanced level of care.

RHCs and FQHCs would continue to be required to provide medical emergency procedures as a first response to common life-threatening injuries and acute illness and to have available the drugs and biologicals commonly used in lifesaving procedures. Even though we are proposing to retain the language in the requirement regarding the availability of drugs and biologicals, we propose to eliminate the prescriptive list of those drugs and biologicals that is currently required. In addition to the drugs and

biologicals that currently are required, we propose that a clinic or center also have available commonly used equipment and supplies for emergency first response procedures that are appropriate for its patient population. Since the proposed conditions are outcome-oriented, we do not believe that we need to specify all the equipment and supplies that a facility should have to accommodate the emergency medical needs of a clinic or center's patients. However, we would expect a clinic or center to have the emergency equipment and supplies that are commonly found in a physician's office or a clinic. Appropriate drugs, biologicals, equipment, and supplies that one would expect to find in a clinic providing emergency first response procedures might include those items that are normally found in an emergency medical crash cart. We believe that most, if not all, clinics and centers would already have these types of supplies in order to provide the emergency services required under the current regulations.

Although we are not specifically proposing to require defibrillators at this time, studies have shown that the appropriate use of defibrillators can save lives. In particular, automated external defibrillators (AEDs) have been shown to save lives in a variety of settings. The key to saving a life is getting the defibrillator on the patient as soon as possible. According to the American College of Emergency Physicians article entitled ''Automatic External Defibrillators,'' June 2003 (*http://www.acep.org/12891.0.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 potential for saved lives supports the financial investment in an AED. Currently, the cost of an AED is approximately $2,000 to $3,000. We are soliciting comments on whether AEDs should be made a regulatory requirement in the future, since RHCs and FQHCs can be located in remote and frontier areas where advanced emergency care might not be available in time to prevent cardiac complications or death.

We also are proposing that staff receive training in the provision of the RHCs or FQHCs emergency procedures. The current requirement does not address this issue. Primary care providers such as physicians, nurse practitioners, physician assistants, nurses, and other allied health personnel often do not frequently receive opportunities to participate in a wide range of emergency care procedures, and, therefore, can benefit from training. At a minimum, we would expect that these professionals are trained in basic life support (BLS). The American Heart Association's (AHA's) guidelines for health care provider courses state that its BLS course teaches the skills of cardiopulmonary resuscitation (CPR) (including ventilation with a barrier device, a bag-mask device, and oxygen) for victims of all ages, and the use of an AED. The course is designed for health care providers that care for patients in a wide variety of settings, both in and out of a hospital.

This basic training may also be augmented by the clinic or center through a variety of means. For example, a facility may elect to provide its own in-service training in emergency procedures or it may choose to use outside resources such as basic trauma life support (BTLS), advanced cardiac life support (ACLS), and pediatric advanced life support (PALS) courses. We encourage clinics and centers to take advantage of these and other existing resources as they determine training needs of personnel providing care to patients.

Additionally, as proposed in § 491.9(c)(3)(iii), a clinic or center would be required to provide training for staff. Because a midlevel practitioner is required to be available to furnish patient care at all times the RHC or FQHC operates, we do not expect the nonprofessional staff to be responsible for providing first response emergency care. However, these individuals would need to be trained in accordance with the facility's policies and procedures related to their roles during the provision of emergency medical services by professional staff. We would expect facilities to determine the best way to train these personnel according to the facilities' individual needs. Facilities may elect to use outside resources such as the AHA's Heartsaver First Aid course, which combines first aid, adult CPR, and AED training, in-service training through the clinic or center's professional staff, or a combination of both. Each facility would be expected to develop its own emergency strategies which are consistent with commonly accepted practice and to document such plans in its written policies.

5. Patient Health Records

RHCs and FQHCs are required to maintain a medical record for each patient receiving health care services. To update patient health record requirements to reflect technological advances in how physicians or other health care professionals sign and authenticate their signatures, we are proposing to update the medical records requirement at § 491.10(a)(3) for RHCs and FQHCs to reflect our requirements and guidelines for other participating providers regarding electronic medical records and electronic signatures.

We propose at § 491.10(a)(3)(v) that all entries (electronic or manual) in the medical record must be legible, complete, dated, timed, and authenticated promptly in written or electronic form by the person responsible for ordering, providing, or evaluating the service furnished. We are also proposing that any entry in the patient health record must be identified and authenticated promptly by the person making the entry. In addition, we are proposing that all entries in the patient health record must be authenticated within 48 hours unless there is a State law that designates a specific timeframe for the authentication of entries.

The identification may include signatures, written initials, or computer entry. If rubber stamp signatures are authorized, the individual whose signature the stamp represents must place in the administrative offices of the RHC or FQHC a signed statement to the effect that he or she is the only individual authorized to use the stamp and may not delegate the stamp to another individual. A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. When rubber stamps or electronic authorizations are used for identification, the RHC must have policies and procedures in place to ensure that stamps or authorizations are used only by the individuals whose signature they represent.

Inherent in these proposed requirements is the idea that there be a specific action by the author to indicate that entries are verified and accurate. Examples of such authentication of entries include: a computerized system that requires the physician to review the document on-line and indicate that it has been approved by entering a computer code; a system in which the physician signs off against a list of entries that must be verified in the individual record; or a mail system in which transcripts are sent to the physician for review, after which he or she signs and returns a postcard identifying the record and verifying its accuracy.

A system of auto-authentication in which a physician or other practitioner authenticates a report before transcription is not consistent with these proposed requirements. There

must be a method of determining that the practitioner in fact did authenticate the document after it was transcribed.

E. Other Proposed Changes

1. General

In addition to the regulatory changes previously described, we propose the following:

- Adding the definition of ''nurse practitioner (NP)'' and ''physician assistant (PA)'' to § 405.2401(b) and removing the definitions from § 491.2 so that RHC/FQHC-related provider definitions are located in the same regulatory section (with the exception of clinical psychologist, which continues to be defined in § 405.2450.)
- Adding the word ''certified'' to the definition of ''nurse-midwife'' in § 405.2401(b) and § 405.2414 to conform to statutory language in sections 1861(aa) and (gg)(2) of the Act.
- Adding the definition of ''clinical social worker'' (CSW) to § 405.2401(b). The definition of ''covered RHC services'' was extended to include the services of a CSW but the definition of a CSW has not been added to the regulations.
- Revising the definition of ''Federally qualified health center'' (FQHC) in § 405.2401(b) to conform the regulations to current statutory requirements.
- Revising the definition of ''rural health clinic'' to § 405.2401(b) and removing the definition from § 491.2 so that it conforms with statutory language in section 1861(aa)(2) of the Act.
- Revising references to the ''Secretary'' in § 405.2404 and § 491.2 to incorporate gender-neutral language.
- Adding the phrase ''CNM, CP, CSW services and supplies'' to § 405.2411 and § 405.2415 to conform to statutory changes in section 1861(aa)(1)(B) and section 1861(aa)(2)(J) of the Act.
- Making additional revisions to § 491.3 to implement proposed certification procedures, in conjunction with the proposed changes to the designation process previously described.
- Revising the heading and introductory text of § 491.4 to make it consistent with the comparable CoP provisions for hospitals and most other providers and to emphasize that the requirements of primary concern are State licensure laws.

2. FQHCs

Section 5114 of the DRA makes a technical correction to section 1861(aa)(4)(A) of the Act by striking the phrase ''(other than subsection (h))'' from that clause. This section of the statute identifies the types of health centers receiving funding under section 330 of the PHS Act that are eligible for Medicare FQHC status. Section 330(h) of the PHS Act, to which the clause refers, addresses Healthcare for the Homeless Health Centers. We are conforming our regulations at § 405.2401 to recognize Healthcare for the Homeless Health Centers as Medicare FQHCs. We also are taking this opportunity to delete obsolete references to sections 329 and 340 of the PHS Act.

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 when a collection of information requirement is submitted to the OMB for review and approval. In order to evaluate fairly whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements (ICRs) discussed below.

A. ICRs Regarding Location of Clinic (§ 491.5)

Proposed § 491.5(b) states that an RHC may be granted an exception to the location requirement specified in § 491.5(a)(1) if the clinic meets the requirements listed in § 491.5(b)(1) through (3). Section 491.5(b)(3) states that an RHC may be granted an exception to the location requirements if it meets the essential provider criteria that are outlined in § 491.5(c). As stated in § 491.5(c), CMS grants essential provider status for a period of 3-years. However, a clinic may reapply for essential provider status if it still needed the exception. An RHC must furnish documentation to demonstrate its compliance with one of the conditions listed in § 491.5(c)(1) through (4).

The burden associated with these proposed requirements is the time and effort necessary for an RHC to submit an application to CMS for an exception to the location requirement. As part of the application, the RHC must collect and submit to CMS the necessary information to support its claim that it meets one of the essential provider criteria listed in § 491.5(c)(1) through (4). We estimate that it would take each RHC 10 hours to collect and submit the necessary information to CMS. The total estimated annual burden associated with this requirement is 5000 hours.

Section 491.5(e)(7) states that at the conclusion of the 3-year exception period, an RHC may renew its essential provider status. The RHC must submit written assurances to the appropriate CMS regional office that it continues to meet the conditions specified in § 491.5. The burden associated with this proposed requirement would be the time and effort necessary to submit written assurances to the appropriate CMS regional office.

We estimate that a total of 500 RHCs would be subject to the requirements contained in § 491.5(e)(7). We estimate that it would take each of the 500 RHCs 1 hour to submit the necessary information to CMS. The estimated annual burden is 500 hours.

B. ICRs Regarding Physical Plant and Environment (§ 491.6)

Proposed § 491.6(d) states that RHCs and FQHCs must protect their patients and staff members by maintaining and documenting an infection control process. The burden associated with this proposed requirement is the time and effort necessary to establish, maintain, and document the infection control process that meets the requirements listed in § 491.6(d)(1) and (2). While these requirements are subject to the PRA, the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). Establishing, maintaining and documenting an infection control program and processes are usual and customary business practices. In addition, maintenance of a documented infection control program is required as part of quality assessment and performance improvement (QAPI) program. The total burden associated with QAPI program requirements is discussed later in Section III.E of the collection of information section of this regulation.

Section 491.6(e) would require clinics or centers to post signs that are noticeable and can be viewed by those with vision problems and those in wheelchairs. The signs must be located at or near the front of the facility. The purpose of the signs is to advise the public of the hours of operation for the center or clinic. The burden associated

with this reporting requirement is the time and effort necessary to create signs and post the signs for the public. While this requirement is subject to the PRA, we believe that the associated burden is exempt as stated in 5 CFR 1320.3(b)(2); posting the signs containing the hours of operation is a usual and customary business practice.

C. ICRs Regarding Staffing and Staff Responsibilities (§ 491.8)

Proposed § 491.8(d) states that a qualified RHC can request a temporary staffing waiver. If the request is approved, the waiver is in effect for a 1-year period. As stated in § 491.8(d)(1), to request a waiver the RHC must demonstrate that it has been unable, despite reasonable efforts in the previous 90-day period, to hire a certified nurse-midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC provides clinical services. The burden associated with this proposed requirement is the time and effort necessary for an RHC to demonstrate to CMS it has been unable to meet the RHC staffing requirements. We estimate that 100 RHCs would apply for waivers on an annual basis. We believe that it would take 3 hours for each RHC to draft its waiver request and demonstrate its inability to meet the staffing requirements. We estimate the total annual burden to be 300 hours.

Proposed § 491.8(d)(3) states that an RHC may submit a request for an additional waiver of staffing requirements no earlier than 6 months after the expiration of the previous waiver. The burden associated with this proposed requirement is the time and effort necessary to submit an additional waiver request. The burden associated with this requirement is explained in our discussion of proposed § 491.8(d)(1).

D. ICRs Regarding Patient Health Records (§ 491.10)

Proposed § 491.10 states that an RHC or an FQHC must maintain a record for each patient receiving health care services. The record must include legible entries that are completed, dated, timed, and authenticated promptly in written or electronic form by the person responsible for ordering, providing, or evaluating the service. All entries in the patient health record must be authenticated within 48 hours unless there is a State law that designates a specific timeframe for the authentication of entries.

The burden associated with these proposed requirements is the time and effort necessary to maintain a patient record. This burden includes the time necessary to record complete, legible entries and to authenticate the record. While these requirements are subject to the PRA, the associated burden is exempt under 5 CFR 1320.3(b)(2). Maintaining and authenticating patient health records is part of usual and customary business practices. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities is exempt from the PRA.

E. ICRs Regarding Quality Assessment and Performance Improvement (§ 491.11)

Section 491.11 would require an RHC to develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. As part of the QAPI program, § 491.11(b)(1)(i) requires an RHC to adopt or develop performance measures that reflect processes of care and RHC operations. Section 491.11(b)(1)(ii) further requires that the RHC use the measures to analyze and track its performance.

Proposed § 491.11(b)(3) states that an RHC must conduct distinct improvement projects. The number and frequency of the distinct improvement projects must reflect the scope and complexity of the clinic's services and available resources. In addition, § 491.11(b)(5) states that an RHC must maintain records on its QAPI program and quality improvement projects.

The burden associated with this proposed requirement would be the time and effort necessary for the RHC to maintain records on its QAPI and quality projects. We estimate that it will take each clinic 1 hour per year to meet this requirement. Since there are an estimated 3,700 facilities, the total burden associated with this requirement would be 3,700 annual hours. The burden associated with this requirement is currently approved under OMB# 0938–0334.

The burden associated with all of the proposed requirements in § 491.11 is the time and effort necessary for an RHC to develop, implement, evaluate, and maintain a QAPI program. We estimate that it would take each of the 3,700 facilities 40 hours to comply with the requirements in § 491.11. We estimate a one-time annual burden of 148,000 to develop a QAPI program.

TABLE 1.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB control number	Respondents	Responses	Total annual burden (hours)
§ 491.5(c)	0938–New	* 500	500	5,000
§ 491.5(e)(7)	0938–New	*500	500	500
§ 491.8(d)	0938–New	100	100	300
§ 491.11	0938–0334	3,700	3,700	** 148,000
Total		4,300	4,300	153,800

* The same 500 respondents are subject to the requirements in both § 491.5(c) and § 491.5(e)(7). They are only counted once in our burden estimate.

** Estimated one-time annual burden.

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 Group, Attn.: William N. Parham, III (Attn: CMS–1910–P2) 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: Carolyn Lovett, CMS Desk Officer, CMS–1910–P2, *Carolyn_Lovett@omb.eop.gov*. Fax (202) 395–6947.

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) (UMRA), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year).

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 to $29 million or less annually (see 65 FR 69432). For purposes of the RFA, all RHCs and FQHCs 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 purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based 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 proposed rule would 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 (Pub. L. 104–4) (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year of $120 million in the aggregate by State, local, or tribal government, or by the private sector. This proposed rule would not mandate any new requirements for State, local or tribal governments, and private sector costs are expected to be less than the $120 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. The proposed rule would not have a substantial effect on State and local governments.

Although we view the anticipated results of these regulations as beneficial to the Medicare and Medicaid programs as well as to Medicare beneficiaries and Medicaid recipients, and State governments, we recognize that some of the provisions could be controversial and may be responded to unfavorably by some affected entities. We also recognize that not all of the potential effects of these provisions can be anticipated definitely, especially in view of the interaction with other Federal, State, and local activities regarding outpatient services. In particular, considering the effects of our simultaneous efforts to improve the delivery of outpatient services, it is impossible to meaningfully quantify a projection of the future effect of all of these provisions on RHCs' and FQHCs' operating costs or on the frequency of substantial noncompliance and termination procedures.

We believe that this regulation would not have a significant financial impact on a substantial number of small entities, such as RHCs and FQHCs. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by the RFA.

B. Anticipated Effects

1. Effects of the Location Requirements on Rural Health Clinics

There are approximately 3,705 participating RHCs. Of these, approximately 500 no longer meet the location requirements for either because they are not in an area designated by the U.S. Census Bureau as nonurban, or they are not designated by the Health Resources and Services Administration as an eligible shortage area. Participating RHCs that no longer are located in rural, underserved areas could lose RHC status and related cost-based reimbursement, potentially causing them to reduce services or discontinue serving Medicare beneficiaries. The estimated Medicare savings associated with the decertification of certain RHCs from the Medicare program are not considered significant.

To minimize the impact of this provision on rural health care, however, the Congress has authorized us to grant, if needed, an exception to clinics determined to be essential to the delivery of primary care in these affected areas. Section 491.5 proposes criteria to determine if an RHC qualifies for an exception to the location requirements. An RHC that is no longer in a valid shortage or is in an urban area may apply for exception from RHC location requirements. Most, but not all, RHCs that apply for an exception are expected to qualify, and would not be decertified based on the location requirements.

Section 4205 of the BBA amended section 1833(f) of the Act to require that provider-based RHCs are subject to the same payment methodology as independent RHCs. Before the BBA, payment to provider-based RHCs was made without considering the number of patient visits provided by the RHC and without a limit on the payment per visit. This already has been implemented through manual instructions and has helped to establish payment equity and consistency within the RHC program. We have codified the statutory requirement to pay all RHCs under an all-inclusive rate per visit, which avoids allocation of excessive administration costs to RHCs, and allow exceptions to the per-visit payment limit for qualifying RHCs.

We believe the fiscal impact of limiting the provider-based RHC payment to the independent RHC rate per visit has resulted in program savings. Provider-based RHCs that have costs above the all-inclusive cost-per-visit limit required by the law may have experienced some decrease in current reasonable cost basis payments. To reduce detrimental impacts of this decrease, section 4205 of the BBA permits an exception to the upper payment limit for RHCs based in small hospitals of less than 50 beds. The number of beds is determined according to the definitions established in § 412.105(b), or an alternative definition established in a Program Memorandum issued September 30, 1998, and updated on December 6, 2001. The alternative bed definition states that a hospital-based RHC can receive an exception to the per visit payment limit if its hospital has fewer than 50 beds as determined by the hospital's average daily census count, is a sole community hospital

located in a level 9–12 UIC, and has an average daily census that does not exceed 40.

There are currently 909 provider-based RHCs whose parent hospital has fewer than 50 beds. Of these, 354 are in UICs 9–12 and are therefore eligible for the exception to the per visit payment limit. By changing to the more accurate RUCAs, approximately 100 of these RHCs would no longer be eligible for the exception to the per-visit payment limit, but 251 previously ineligible RHCs would be eligible. This would result in a net total of 505 RHCs eligible for the exception to the per visit payment limit, a gain of 151. We expect that the RHCs that would gain eligibility to the payment limit exception would be in more rural areas that have greater financial challenges. Therefore, the fiscal impact of this change is expected to be minimal.

The QAPI requirement may increase burden in the short term because resources currently used for the required evaluation of the clinic's programs would need to be directed to the development of a QAPI program that covers the complexity and scope of the particular clinic. Although the requirements may result in some immediate costs to an individual clinic, we believe that the QAPI program would result in real, but difficult to estimate, long-term economic benefits to the clinic (for example, cost-effective performance practices or higher patient satisfaction that may lead to increased patient visits for the clinic).

Further, the QAPI and utilization review requirements replace the current annual evaluation requirement. Resources that the clinics currently are using for the annual evaluation could be devoted to the QAPI program. Therefore, we believe that there would be no long-term increased burden on the clinics. Currently, a number of RHCs, primarily provider-based, have some type of quality improvement program in place. To the extent that a clinic is familiar with collecting data on its operations and measuring quality, the new requirement should not impose significant additional burden.

2. Impact of the QAPI Provisions

We estimate that the additional one-time impact for the initial development of the QAPI provisions would be as Shown in Table 2.

TABLE 2

Hours/estimated salary/number of RHCs	One-time Cost	Annual cost
1 physician/administrator at $58/hr × 3 hrs × 3,300 clinics for medical direction and overview of QAPI program	$574,200	.....
1 Mid-level practitioner (physician assistant, nurse practitioner) at $28/hr × 32 hrs × 3,300 clinics for program development	2,956,800	.....
1 clerical staff at $6/hr × 5 hrs × 3,300 clinics	99,000	.....
1 mid-level practitioner at $28/hr × 4 hrs × 3,300 clinics for data collection and analysis.	.....	369,600
1 mid-level practitioner—3 hrs training	.....	277,200
Totals	3,630,000	646,800

To develop our estimates, we used information on the salaries and wage estimation obtained from the American Medical Association.

OBRA '89 reduced the nonphysician staffing requirement for RHC qualification from 60 percent to 50 percent. This reduction should have a positive effect on RHCs by providing them more flexibility in satisfying overall staffing needs.

3. Effects on Other Providers

We are aware of situations in which an RHC and a physician's private practice occupy the same space and bill Medicare for services either as an RHC or as a physician, depending upon which payment method produces the greater payment. Our revision would require an RHC to be a distinct entity that is not used simultaneously as a private physician office or the private office of any other health care professional. As a result, private physicians or other practitioners who have used this approach under the Medicare program may experience some change in the operation of their practices from an administrative standpoint.

4. Effects on the Medicare and Medicaid Programs

As a result of this proposed rule, some existing RHCs would be at risk of losing their RHC status. We believe that any aggregate changes to overall spending would be negligible. This proposed rule would also result in some RHCs losing their exception to the per visit payment limit, while other RHCs would become eligible for the exception to the per visit payment limit. We cannot estimate accurately the payment differential since the clinics vary in terms of size and patient visits.

However, we believe that since total expenditures for this program represent a small fraction of the Medicare and Medicaid total budget and less than 20 percent of all RHCs would experience changes to payment rates, any aggregate savings would be insignificant. We also believe an insignificant amount of Medicare and Medicaid program savings would result from the provision that would terminate RHC status for certain providers. An RHC that loses its eligibility to participate in the RHC program likely would choose to participate in the Medicare and Medicaid programs in a non-RHC capacity such as a physician-directed clinic or a group of individual practitioners who would then bill Medicare using the Part B fee-for-service system.

C. Alternatives Considered

Section 4205 of the BBA imposes new requirements that the RHC program must meet. We considered some of the following alternatives to implement these provisions:

1. ''Essential'' RHCs

Since the statute mandates an exception process for essential clinics, we considered using a national utilization test to recognize clinics that are accepting and treating a disproportionately greater number of Medicare, Medicaid, and uninsured patients in comparison to other participating RHCs, for the purpose of addressing the situation of RHC clusters. For example, using an aggregate threshold based on the average Medicare, Medicaid, and uninsured utilization rates of participating RHCs, an applicant would have to demonstrate that its utilization rates exceed the threshold.

Although this test would be administratively feasible, we concluded, based on our analysis of available Medicare and Medicaid RHC data, that it would not determine accurately

''essential'' clinics at the community level because of the wide variability in the percentage of services furnished to Medicare and Medicaid patients by RHCs. Despite our rejection of a national utilization test, we are open to suggestions on developing a minimum national percentage, which could be integrated with our major community provider test. We also considered the option of establishing less generous tests for identifying RHCs as essential clinics to the delivery of primary care. That is, we considered the establishment of tests narrowly focused on a few extreme cases, such as an exception test for only sole community providers. We rejected this option because of concern that the decertification of a clinic from the RHC program could decrease access to primary care for the entire community. We believe several options should be available to reflect the variability of communities in providing access to care for rural areas.

2. QAPI Program

Because the statute mandates that an RHC have a QAPI program, and appropriate procedures for review of utilization of clinic services, no alternatives for the requirement were considered. However, in the preamble of the February 28, 2000, proposed rule, we described alternative ways of satisfying the ''minimum level requirement'' for the QAPI program and requested public comment. We considered the following alternatives:

- Require RHCs to engage in an improvement project in three specified domains annually.
- Require a minimum number of improvement projects in any combination of the specified domains annually.
- Require a minimum number of projects annually based on patient population.
- Rather than requiring a minimum number of projects, require RHCs to demonstrate to the State Survey Agency what projects they are doing and what progress is being achieved.

After considering the public comments, which were not conclusive, we decided not to establish a minimum requirement. As we noted in the December 24, 2003, final rule, we did consider alternatives for the rule. One alternative was to take a more rigid approach, whereby the final rule would be more prescriptive in the process that RHCs must follow to develop the QAPI program, to include setting forth specific performance measures to be used, the frequency and number of QAPI ''interventions'' that must be done, and the type and frequency of data to be collected. While a more rigid approach would increase RHC burden, we realize there would be no assurance that it would result in better or more predictable outcomes.

We decided to promote a more flexible and less prescriptive approach to the QAPI condition. We are more concerned with an RHC identifying its own best practices and the outcomes of an RHC's individualized QAPI program than in specific steps the RHC takes to achieve the improvement. A more moderate QAPI requirement would allow an RHC the flexibility to use staff and other resources in ways that more directly support its needs. An RHC can design a program to analyze its own organizational processes, functions, and services, while still being held accountable for results. This decision would allow each RHC the flexibility to fulfill this requirement based on its resources.

D. Conclusion

We do not expect a significant change in the operations of RHCs or FQHCs generally, nor do we believe a substantial number of small entities in the community, including RHCs, FQHCs, and a substantial number of small rural hospitals, would be affected adversely by these changes.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the 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 410

Health facilities, health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

1. The authority citation for subpart X continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 405.2401(b) is amended by—

A. Adding the definitions of ''clinical social worker'' and ''employee'' in alphabetical order.

B. Republishing the introductory text of the definition of ''Federally qualified health center'' and revising paragraph (1) of that definition.

C. Adding the word ''Certified'' before ''Nurse-midwife'' in the definition of ''Nurse-midwife,'' changing the ''N'' of ''Nurse-midwife'' to lower case, and putting the definition in alphabetical order.

D. Removing the definition of ''nurse practitioner and physician assistant''.

E. Adding the definitions of ''nurse practitioner'' and ''physician assistant'' in alphabetical order.

F. Revising the definition of ''rural health clinic.''

The revisions and additions read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Clinical social worker (CSW) means an individual who has the following qualifications:

(1) Possesses a doctoral or master's degree in social work.

(2) After obtaining a doctoral or master's degree in social work, has performed at least 2 years of supervised clinical social work.

(3) Either is licensed or certified as a CSW by the State in which the individual practices or, in the case of an individual in a State that does not provide for licensure or certification, has completed at least 2 years or 3,000 hours of post-master's degree clinical social work practice under the supervision of a qualified master's degree social worker in an appropriate setting such as a hospital, clinic, or SNF.

(4) Is employed by or under contract with the RHC or FQHC to furnish diagnostic and therapeutic mental health services.

* * * * *

Employee means any individual who, under the common law rules that apply

in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under § 405.2434 and—

(1) Is receiving a grant under section 330 of the Public Health Service (PHS) Act, or is receiving funding from such a grant under a contract with a recipient of such a grant and meets the requirements to receive a grant under section 330 of the PHS Act;

* * * * *

Nurse practitioner (NP) means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has satisfactorily completed a formal academic 1-year educational program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

* * * * *

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that meets all of the following requirements:

(i) Was at least 1 academic year in length.

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care.

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

* * * * *

Rural health clinic (RHC) means an entity that meets the following requirements:

(1) The requirements specified in section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval.

(2) Has filed an agreement with CMS that meets the basic requirements described in § 405.2402 to provide RHC services under Medicare.

* * * * *

§ 405.2402 [Amended]

3. Amend § 405.2402(d) by removing ''he'' and adding ''the Secretary'' in its place.

§ 405.2404 [Amended]

4. Amend § 405.2404(a)(2)(ii) by removing ''he'' and adding ''the Secretary'' in its place.

5. Revise § 405.2410 to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for RHC services begins only after the beneficiary has incurred the deductible. Medicare applies the Medicare Part B deductible as follows:

(i) If the deductible is fully met by the beneficiary before the RHC visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible is not fully met by the beneficiary before the visit and the amount of the RHC's reasonable customary charge for the service that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-inclusive rate and 80 percent of the remainder, if any, is paid to the RHC; or

(B) Equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(2) Medicare payment for FQHC services is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* The beneficiary is responsible for the coinsurance amount.

(1) For any one service provided by an RHC—

(i) If the deductible has already been met, beneficiary coinsurance liability must not exceed 20 percent of the clinic's reasonable customary charge for the covered service;

(ii) If the deductible has not already been met, the beneficiary coinsurance liability must not exceed 20 percent of any remainder amount after deducting the unmet deductible from the clinic's reasonable customary charge for the covered service.

(2) The beneficiary's deductible and coinsurance liability for any one service furnished by the RHC may not exceed 20 percent of the reasonable amount customarily charged by the RHC for that particular service.

(3) Except for services provided under Medicare Advantage plans to FQHCs in accordance with section 1833(a)(3)(B) of the Act, the coinsurance liability may not exceed 20 percent of the reasonable amount customarily charged by the FQHC for the particular service.

6. Section 405.2411 is amended by—

A. Revising paragraph (a) introductory text.

B. Amending paragraphs (a)(1) through (a)(3) by removing the ''; '' at the end of each paragraph and adding a ''.'' in its place.

C. Amending paragraph (a)(4) by removing the ''; and'' at the end of the paragraph and adding ''.'' in its place.

D. Adding new paragraphs (a)(6) through (a)(8).

E. Revising paragraph (b).

F. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 405.2411 Scope of benefits.

(a) Rural health clinic services reimbursable under this part are as follows:

* * * * *

(6) Certified nurse-midwife (CNM) services.

(7) Clinical psychologists (CP) and clinical social worker (CSW) services specified in § 405.2450 of this subpart.

(8) Service and supplies furnished as an incident to CP or CSW services, as specified in § 405.2452 of this subpart.

(b) RHC services are covered when furnished in an RHC setting or other

outpatient setting, including a patient's place of residence or a skilled nursing facility.

(c) RHC services are not covered in a hospital, as defined in section 1861(e)(1) of the Act, or a critical access hospital.

7. Section 405.2414 is amended by—

A. Revising the section heading.

B. Revising paragraph (a)(1).

C. Adding the word ''certified'' before ''nurse-midwife'' in paragraph (a)(4).

D. Adding the word ''certified'' before ''nurse-midwives'' in paragraph (c).

The revisions read as follows:

§ 405.2414 Nurse practitioner (NP), physician assistant (PA), and certified nurse-midwife (CNM) services.

(a) * * *

(1) Furnished by a nurse practitioner, physician assistant or certified nurse-midwife, who is employed by, or receives compensation from, the rural health clinic;

* * * * *

8. Amend § 405.2415 by—

A. Revising the section heading.

B. Revising the introductory text of paragraph (a).

C. Revising paragraph (a)(4).

D. Revising paragraph (b).

The revisions read as follows:

§ 405.2415 Services and supplies incident to a clinical psychologist (CP), clinical social worker (CSW), nurse practitioner (NP), physician assistant (PA), or certified nurse mid-wife (CNM) services.

(a) Services and supplies incident to a clinical psychologist's or clinical social worker's, nurse practitioner's, physician assistant's, or certified nurse-midwife's services are reimbursable under this subpart if the service or supply is—

* * * * *

(4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, certified nurse-midwife, clinical psychologist, clinical social worker, or physician; and

* * * * *

(b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, certified nurse-midwife, nurse practitioner, clinical psychologist, or clinical social worker only if the person is permitted to supervise those services under the written policies governing the RHC.

* * * * *

§ 405.2448 [Amended]

9. Amend § 405.2448 by removing and reserving paragraph (d).

10. Section 405.2462 is revised to read as follows:

§ 405.2462 Payment for rural health clinic services and Federally qualified health center services.

(a) *General rules.* (1) RHCs and FQHCs are paid on the basis of an all-inclusive rate per visit, subject to a payment limit.

(2) The Medicare Administrative Contractor or fiscal intermediary determines the all-inclusive rate in accordance with this subpart and instructions issued by CMS.

(b) *Rules for RHCs.* RHCs must meet the following requirements:

(1) Does not share space, staff, supplies, records, and other resources during RHC hours of operation with a private Medicare or Medicaid approved or certified practice owned, controlled or operated by the same physicians and nonphysician practitioners that staff the RHC as employees or contractors; and

(2) If sharing a multipurpose clinic with other types of health providers or suppliers, appropriately allocates and excludes from the RHC cost report the net non-RHC costs associated with the sharing of common space, medical support staff, or other physical resources.

(3) If an RHC is an integral and subordinate part of a hospital, it can receive an exception to the per visit payment limit if the hospital has fewer than 50 beds as determined by using one of the following methods:

(i) The determination of the number of beds at § 412.105(b) of this chapter.

(ii) The hospital's average daily patient census count of those beds described in § 412.105(b) of this chapter and the hospital meets all of the following conditions:

(A) It is a sole community hospital as determined in accordance with § 412.92 or essential access community hospital as determined in accordance with § 412.109(a) of this chapter.

(B) It is located in a level 9 or 10 Rural-Urban Commuting Area (RUCA).

(C) It has an average daily patient census that does not exceed 40.

(c) *Payment procedures.* To receive payment, an RHC or FQHC must follow the payment procedures specified in § 410.165(a) of this chapter.

(d) *Mental health limitation.* Payment for the outpatient treatment of mental, psychoneurotic, or personality disorders is subject to the limitations on payment in § 410.155 of this chapter.

11. In § 405.2466 paragraph (b)(1)(iii) is revised to read as follows:

§ 405.2466 Annual reconciliation.

* * * * *

(b) * * *

(1) * * *

(iii) Medicare payment to the RHC or FQHC is equal to its reasonable costs less aggregate coinsurance and deductible amounts billable, but in no case may total Medicare payment exceed 80 percent of reasonable costs.

* * * * *

§ 405.2468 [Amended]

12. In § 405.2468 paragraph (b)(1) is revised by removing the parenthetical statement ''(RHCs are not paid for services furnished by contracted individuals other than physicians.)''

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

13. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

14. Section 410.150 is amended by—

A. Revising the first sentence of paragraph (b)(15).

B. Adding a new paragraph (b)(20).

The revision and addition read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(15) Except for certain physician assistant services provided in a rural health clinic owned by a physician assistant, as specified in paragraph (b)(20) of this section, to the qualified employer of a physician assistant for professional services furnished by the physician assistant and for services and supplies furnished incident to his or her services. * * *

* * * * *

(20) To a physician assistant who was the owner of a rural health clinic as described § 405.2401(b) of this subchapter. Payment is made to such physician assistant for services and supplies furnished incident to his or her services only if—

(i) No facility, other provider charges, or other amount has been paid for services furnished by such physician assistant; and

(ii) The physician assistant owned the rural health clinic for a continuous period beginning on or before August 4, 1997 and ending on the date that the Secretary determines that the clinic no longer meets the requirements of section 1861(aa)(2) of the Act.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

15. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

16. Section 491.2 is revised to read as follows:

§ 491.2 Definitions.

As used in this subpart, unless the context indicates otherwise:

Certified nurse-midwife (CNM), clinical social worker (CSW), nurse practitioner (NP), physician, and physician assistant (PA) mean an individual who has the qualifications for such practitioner set forth in § 405.2401 of this chapter.

Clinical psychologist (CP) means an individual who has qualifications as defined in § 405.2450 of this chapter.

Nonurban area means an area that is not delineated as an urbanized area by the U.S. Census Bureau.

Rural area means an area that is not delineated as an urbanized area by the U.S. Census Bureau.

Rural health clinic means a facility as defined in § 405.2401(b).

Shortage area means a geographic area that meets one of the following criteria:

(1) Designated by the Secretary as a geographic primary care health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (PHS Act);

(2) Designated by the Secretary as a population group primary care HPSA under section 332(a)(1)(B) of the PHS Act;

(3) Designated by the Secretary as a medically underserved area (but not as a medically underserved population group) under section 330(b)(3) of the PHS Act; or

(4) Designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services under section 6213(c) of the Omnibus Budget Reconciliation Act of 1989.

17. Section 491.3 is revised to read as follows:

§ 491.3 General certification requirements.

(a) *General.* (1) RHCs participate in Medicare in accordance with an agreement as specified in § 405.2402 through § 405.2404 of this chapter.

(2) If CMS approves or disapproves the participation request of a prospective RHC, CMS notifies the appropriate State agency.

(3) CMS deems an entity that is approved for Medicare participation as an RHC to meet the standards for certification under Medicaid.

(b) *Permanent and mobile units.* An RHC and an FQHC may be located in a permanent or a mobile unit.

(1) *Permanent unit.* The objects, equipment, and supplies necessary for the provision of services furnished directly by the clinic or center are housed in a permanent structure.

(2) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of services furnished directly by the clinic or center are housed in a mobile structure, which has fixed, scheduled locations.

(3) *Permanent unit in more than one location.* If the RHC or FQHC services are furnished at permanent units in more than one location, each unit is independently considered for certification as an RHC or FQHC and must meet the location requirements based on the physical location of the clinic or center.

18. Section 491.4 is revised to read as follows:

§ 491.4 Compliance with State licensure laws.

The RHC or FQHC and its staff meet applicable Federal laws related to the health and safety of patients as well as State licensure requirements.

19. Section 491.5 is amended by revising paragraphs (a) through (e) to read as follows:

§ 491.5 Location of clinic.

(a) *General location requirements.*

(1) An existing RHC or an applicant requesting entrance into the Medicare program as an RHC—

(i) Is located in a rural area that is currently designated as a shortage area as defined in § 491.2; and

(ii) The designation of such shortage area has been made or updated during the past 3 years.

(2) An FQHC is located in a rural or urban area that is designated as either a medically underserved area or includes a medically underserved population group.

(b) *Location exception requirements.* An RHC may be considered for an exception to the location requirements specified in § 491.5(a)(1) if the clinic—

(1)(i) Is in an area currently classified by the U.S. Census Bureau as an urbanized area; or

(ii) Is in an area not currently designated as a shortage area.

(2)(i) Is located in an area that has been classified as an Urbanized Area by the U.S. Census Bureau and is in a level 4 or higher RUCA; and

(ii) Demonstrates that at least 51 percent of the clinic's patients reside in an adjacent nonurbanized area.

(3) Meets the essential provider criteria specified in paragraph (c) of this section.

(c) *Essential provider criteria.* CMS grants essential provider status is for a period of 3 years. At the end of the 3-year period, the clinic may reapply for continued essential provider status if an exception is still needed. To receive an exception to the location requirements, an RHC must provide documentation to support that it meets one of the following conditions:

(1) *Sole community provider.* The RHC is the only participating primary care provider that meets either of the following criteria:

(i) Is at least 25 miles from the nearest participating primary care provider.

(ii) Is at least 15 miles but less than 25 miles from the nearest participating primary care provider and demonstrates that it is more than 30 minutes from the nearest primary care provider based on local topography, predictable weather conditions, or posted speed limits. For purposes of this exception, a participating primary care provider means another RHC, FQHC, or other primary care provider that actively is accepting and treating Medicare, Medicaid, low-income and uninsured patients (regardless of their ability to pay).

(2) *Major community provider.* The RHC must meet the following conditions to be considered a major community provider:

(i) Has a Medicare, Medicaid, low-income and uninsured patient utilization rate greater than or equal to 51 percent or a low-income patient utilization rate greater than or equal to 31 percent.

(ii) Is actively accepting and treating a major share of the Medicare, Medicaid, low-income, and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers that are within 25 miles of the RHC.

(3) *Specialty clinic: Obstetrics/gynecology (ob/gyn) or pediatrics.* The RHC must meet all the following conditions to be considered a specialty clinic:

(i) Exclusively provides ob/gyn or pediatric health services.

(ii) Is the sole provider or major source of ob/gyn or pediatrics health services for Medicare (when applicable), Medicaid, low-income, and uninsured patients (regardless of their ability to pay) and that meets either of the following conditions:

(A) Is at least 25 miles from the nearest participating primary care provider of ob/gyn or pediatric services; or

(B) Is at least 15 miles but less than 25 miles from the nearest participating primary care provider of ob/gyn or pediatric services and can demonstrate that it is more than 30 minutes from the nearest primary care provider providing these services based on local

topography, predictable weather conditions, or posted speed limits.

(iii) Is actively accepting and treating Medicare (where applicable), Medicaid, low-income, and uninsured patients;

(iv) Has a Medicare, Medicaid, low-income patient and uninsured patient utilization rate greater than or equal to 31 percent.

(v) Provides ob/gyn or pediatric health services onsite to clinic patients.

(4) *Extremely rural community provider*. The RHC must meet the following conditions to be considered an extremely rural community provider:

(i) Is actively accepting and treating Medicare, Medicaid, low-income, and uninsured patients (regardless of their ability to pay).

(ii) Is located in a frontier county (6 or less persons per square mile) or in a Rural-Urban Commuting Area level 10 area.

(d) *Termination*. (1) CMS decertifies a clinic from participation in the Medicare program as an RHC, effective 180 days after the date that the RHC no longer meets the location requirements, unless—

(i) An application to update the shortage area designation has been received by the Health Resources and Services Administration (HRSA) not later than 3 years from the date of the last designation; or

(ii) The RHC has submitted an application for an exception to the location requirement as specified in paragraph (e) of this section and meets the exception standards set forth in paragraphs (b) and (c) of this section.

(2) CMS may terminate RHC status at any time if it determines that the RHC is not in compliance with any certification requirements.

(e) *Process for essential provider status*.

(1) If HRSA has not received an application to update a designation by the end of the 3 years from the date of the previous designation, an RHC in such area has 90 days from the end of the 3-year period to submit its request to CMS for an exception in order to continue to be considered to be an essential provider.

(2) If HRSA has proposed for withdrawal or withdrawn a designation, the RHC in such area must submit its request to CMS for an exception in order to continue to be considered an essential provider 90 days from the date the designation was proposed for withdrawal or withdrawn.

(3) If HRSA has disapproved an application to update a designation, the RHC in such area has 90 days from the date of the disapproval to submit a request for a location exception in order to be considered an essential provider.

(4) An existing RHC may apply for an exception from decertification by submitting to the appropriate CMS regional office a written request with any necessary documentation demonstrating that it meets one of the essential provider criteria specified in paragraph (c) of this section.

(5) CMS does not decertify an RHC that has submitted an application for an exception within 90 days from the date that the RHC no longer meets the location requirements while the application for an exception is under review, for a period not to exceed 180 days from the date the RHC no longer meets the location requirement, or the effective date of the final rule, whichever is later. In rare circumstances, the CMS RO may request an extension from the CMS Central Office if it has not been possible to process the location exception request before the RHC would be decertified.

(6) The CMS regional office may grant a 3-year exception based on its review of an RHC request and other relevant information, if such CMS regional office determines that the RHC is essential to the delivery of primary care services that otherwise are not available in the geographic area served by the RHC, as specified in paragraph (b) of this section.

(7) At the end of the 3-year exception period, a clinic may renew its essential provider status by submitting written assurances to the appropriate CMS regional office that it continues to meet the conditions specified in this section.

(8) An RHC that is located in an area for which an application to update the designation has not been submitted to HRSA or has been found by HRSA to not qualify for an eligible designation, and has not submitted an application for an exception within 90 days of the date that the designation is more than 3 years old, may continue to operate as an RHC for 180 calendar days after the expiration of the applicable 3-year period, effective the last day of the month.

(9) A provider-based RHC that does not meet the location requirements and does not qualify for an exception and has submitted an application to CMS to be another type of Medicare provider that requires a State survey for certification, may receive an additional 120 days extension of their status as an RHC while their application is being processed.

* * * * *

20. Section 491.6 is amended by—

A. Adding paragraph (d).

B. Adding paragraph (e).

The additions read as follows:

§ 491.6 Physical plant and environment.

* * * * *

(d) *Infection control*. The RHC or FQHC must protect patients and staff by maintaining and documenting an infection control process that—

(1) Follows accepted standards of practice, including the use of standard precautions, to prevent the transmission of infectious and communicable diseases; and

(2) Is an integral part of the quality assessment and performance improvement (QAPI) programs.

(e) *Hours of operation*. The clinic or center must post signs that are noticeable and can be viewed by those with vision problems and those in wheelchairs at or near the entrance to the facility to advise the public of the days of the week and hours when services are furnished.

21. Section 491.8 is amended by—

A. Revising paragraphs (a)(1), (a)(3), and (a)(6).

B. Adding paragraph (d).

The revisions and additions read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

(1) (i) RHC or FQHC has a health care staff that includes one or more physicians.

(ii) A RHC must employ one or more physician assistants or nurse practitioners.

* * * * *

(3) The physician assistant, nurse practitioner, certified nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center.

* * * * *

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

* * * * *

(d) *Temporary staffing waiver*. (1) CMS may grant a temporary waiver of the RHC staffing requirements in paragraphs (a)(1)(ii) and (a)(6) of this section for a 1-year period to a qualified RHC, if the RHC requests a waiver and demonstrates that it has been unable,

despite reasonable efforts in the previous 90-day period, to hire a certified nurse-midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC provides clinical services, or to hire a PA or NP as a direct employee.

(2) CMS terminates the RHC from participation in the Medicare program, if the RHC is not in compliance with the provisions waived under paragraphs (a)(1) and (a)(6) of this section at the expiration of the waiver.

(3) The RHC may submit its request for an additional waiver of staffing requirements under this paragraph no earlier than 6 months after the expiration of the previous waiver.

22. Section 491.9 is amended by—

A. Revising paragraph (c)(2).

B. Revising paragraph (c)(3).

The revisions and addition read as follows:

§ 491.9 Provision of services.

* * * * *

(c) * * *

(2) *Laboratory*. These requirements apply to RHCs but not to FQHCs. The clinic provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient. See § 405.2462 of this chapter for payment requirements for clinical laboratory services furnished within the RHC setting. These laboratory services include the following:

(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones).

(ii) Hemoglobin or hematocrit.

(iii) Blood glucose.

(iv) Examination of stool specimens for occult blood.

(v) Pregnancy tests.

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Emergency*. The clinic or center must—

(i) Provide medical emergency procedures as a first response to common life-threatening injuries and acute illnesses;

(ii) Have available the drugs, biologicals, equipment, and supplies, which are appropriate for the facility's patient population and which are commonly used in emergency first response procedures; and

(iii) Provide training for staff in the provision of these emergency procedures according to the clinic's or center's policies that are consistent with commonly accepted practice as well as in accordance with applicable Federal, State, and local laws.

* * * * *

23. Section 491.10 is amended by—

A. Revising paragraph (a)(3) introductory text.

B. Removing the '';'' at the end of paragraphs (a)(3)(i) through (a)(3)(iv) and adding a ''.'' in its place.

C. Adding a new paragraph (a)(3)(v).

The revision and addition read as follows:

§ 491.10 Patient health records.

(a) * * *

(3) For each patient receiving RHC or FQHC services at such facility, the RHC or FQHC maintains a record that includes the following, as applicable:

* * * * *

(v) Legible entries that are completed, dated, timed, and authenticated promptly in written or electronic form by the person responsible for ordering, providing, or evaluating the service. Any entry in the patient health record must be identified and authenticated promptly by the person making the entry. All entries in the patient health record must be authenticated within 48 hours unless there is a State law that designates a specific timeframe for the authentication of entries.

* * * * *

24. Revise § 491.11 to read as follows:

§ 491.11 Quality assessment and performance improvement for RHCs.

The RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. The self-assessment and performance improvement program must be appropriate for the complexity of the RHCs organization and services and focus on maximizing outcomes by improving patient safety, quality of care, and patient satisfaction.

(a) *Standard: Components of a QAPI program*. The RHC's QAPI program must include, but not be limited to, the use of objective measures to evaluate the following:

(1) Organizational processes, functions, and services.

(2) Utilization of clinic services, including at least the number of patients served and the volume of services.

(b) *Standard: Program activities*. (1) For each of the areas listed in paragraph (a)(1) of this section, the RHC must do the following:

(i) Adopt or develop performance measures that reflect processes of care and RHC operation and are shown to be predictive of desired patient outcomes or to be the outcomes themselves.

(ii) Use the measures to analyze and track its performance.

(2) The RHC must set priorities for performance improvement, considering either high-volume, high-risk services, the care of acute and chronic conditions, patient safety, coordination of care, convenience and timeliness of available services, or grievances and complaints.

(3) The RHC must conduct distinct improvement projects. The number and frequency of distinct improvement projects conducted by the RHC must reflect the scope and complexity of the clinic's services and available resources.

(4) An RHC that develops and implements an information technology system explicitly designed to improve patient safety and quality of care meets the requirement for a project under this section.

(5) The RHC must maintain records on its QAPI program and quality improvement projects.

(c) *Standard: Program responsibilities*. The RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for the following:

(1) Identifying or approving QAPI priorities.

(2) Ensuring that QAPI activities that are developed to address identified priorities are implemented and evaluated.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 11, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 28, 2008.

Michael O. Leavitt,

Secretary.

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Part IV

Department of Justice

Drug Enforcement Administration

21 CFR Parts 1300, 1304, et al.
Electronic Prescriptions for Controlled Substances; Proposed Rule

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1304, 1306, and 1311

[Docket No. DEA–218P]

RIN 1117–AA61

Electronic Prescriptions for Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: DEA is proposing to revise its regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. These regulations would also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These proposed regulations would be an addition to, not a replacement of, the existing rules. These regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances dispensing; additionally, the proposed regulations would reduce paperwork for DEA registrants who dispense or prescribe controlled substances and have the potential to reduce prescription forgery. The proposed regulations would also have the potential to reduce the number of prescription errors caused by illegible handwriting and misunderstood oral prescriptions. Moreover, they would help both pharmacies and hospitals to integrate prescription records into other medical records more directly, which would increase efficiency, and would reduce the amount of time patients spend waiting to have their prescriptions filled.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before September 25, 2008.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–218'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov*. Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept electronic comments containing MS word, WordPerfect, Adobe PDF, or Excel files only. DEA will not accept any file formats other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

I. Background

Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1399. These regulations are designed to ensure an adequate supply of controlled substances for legitimate medical, scientific, research, and industrial purposes, and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity.

Controlled Substances

Controlled substances are drugs that have a potential for abuse and psychological and physical dependence; these include opiates, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances. DEA lists controlled substances in 21 CFR part 1308. The substances are divided into five schedules: Schedule I substances have a high potential for abuse and have no accepted medical use in treatment in the United States. These substances may only be used for research, chemical analysis, or manufacture of other drugs. Schedule II–V substances have accepted medical uses and also have potential for abuse and psychological and physical dependence. Virtually all Schedule II–V controlled substances are available only under a prescription written by a practitioner licensed by the State and registered with DEA to dispense the substances. Overall, controlled substances constitute between 10 percent and 11 percent of all prescriptions written in the United States.

History

The CSA and DEA's regulations were originally adopted at a time when most transactions and particularly prescriptions were done on paper. The CSA mandates that some records must be created and kept on forms that DEA provides and that many controlled substance prescriptions must be manually signed. In 1999, in response to requests from the regulated community, DEA began to examine how to revise its regulations to allow the use of electronic systems within the limits imposed by the statute and mindful that the records had to be usable in legal actions. On April 1, 2005, after extensive consultation with the regulated community, DEA published a final rule that allowed the electronic creation, signature, transmission, and retention of records of orders for Schedule I and II controlled substances, orders that prior to that time had to be created on preprinted forms that DEA issued (70 FR 16901, April 1, 2005).

At the same time, DEA began to examine how to revise its rules to allow electronic prescriptions for controlled substances. In addition to complying with the mandates of the CSA, regulations on electronic prescriptions must be consistent with other statutory mandates and Federal regulations. The Electronic Signatures in Global and National Commerce Act of 2000, commonly known as E-Sign, was signed into law on June 30, 2000 (Pub. L. 106–229). It establishes the basic rules for using electronic signatures and records in commerce. E-Sign was enacted to encourage electronic commerce by giving legal effect to electronic signatures and records and to protect consumers. E-Sign provides that, with respect to any transaction in or affecting interstate or foreign commerce, a signature may not be denied legal effect solely because it is in electronic form (15 U.S.C. 7001(a)). However, E-Sign further provides that, where a statute or regulation requires retention of a record, and an electronic record is used to meet such requirement, Federal, State, and local agencies may set performance standards to ensure accuracy, record integrity, and accessibility of records (15 U.S.C. 7004(b)(3)(A)). Such performance standards may be specified in a manner that requires the implementation of a specific technology if such requirement serves an important governmental objective and is substantially related to that objective interest (Id.).

In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Pub. L. 108–173). Section 1860D–4(e) (codified at 42 U.S.C. 1395w–104(e)) contains the requirement that the electronic transmission of prescriptions and prescription-related information for covered Part D drugs prescribed for Part D eligible individuals comply with final uniform standards adopted by the Secretary of the Department of Health and Human Services (HHS). One of the considerations in support of this move to electronic prescriptions was the view that using electronic prescriptions in lieu of written or oral prescriptions could reduce medical errors that occur because handwriting is illegible or phoned in prescriptions are misunderstood as a result of similar sounding medication names. Another consideration is that, if prescription records are linked to other medical records, practitioners can be alerted at the time of prescribing to possible interactions with other drugs the patient is taking or allergies a patient might have. Electronic prescribing systems also can link to insurance formulary lists to inform the practitioner prior to prescribing whether a drug is covered by a patient's insurance.

HHS adopted a rule on the transmission standard for electronic prescriptions in November 2005 (70 FR 67593, November 7, 2005) and revised it on June 23, 2006 (71 FR 36023). The standard focuses on the format for the transmitted information, not with the process of creating the prescription or maintaining the record at the pharmacy. HHS adopted the National Council of Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 8.1. The standard specifies fields (name, date, address, etc.) and field lengths for certain transactions including issuing new prescriptions and refills. The rule applies to prescriptions issued to patients under Part D (the prescription drug program for Medicare patients). The rule does not require practitioners or pharmacies to use electronic prescriptions, but rather requires that companies that sponsor Part D coverage establish and maintain an electronic prescription program that meets the standard. The purpose of the standard is to ensure that electronic prescriptions are created and transmitted in a format that can be read by the receiving pharmacy (i.e., that the systems creating, transmitting, and receiving the prescriptions are interoperable).

The rule DEA is hereby proposing has been written to be consistent with the foregoing HHS standard. However, it bears emphasis that the context in which the HHS standard was issued was not specific to controlled substances and therefore not designed to provide safeguards against the diversion of controlled substances. The responsibility for establishing regulatory safeguards against diversion of controlled substances falls upon DEA as the agency charged with administering and enforcing the CSA. Accordingly, while the rule being proposed here by DEA is designed to work in tandem with the HHS standard, its scope is necessarily distinct from the HHS standard.

Prescription records and transmission are also subject to the Health Insurance Portability and Accountability Act (HIPAA), which establishes protection for health information. Any party to the creation, transmission, and storage of prescriptions must meet standards to ensure that the information is protected and not revealed to persons who are not authorized to see it. Health Plans, Health Care Clearinghouses, and covered Health Care Providers that are involved in the transmission of prescriptions must comply with HIPAA standards, which are codified at 45 CFR parts 160, 162, and 164. Because of the wide variety of healthcare providers subject to HIPAA, the requirements are general to allow the providers to adopt protections that are appropriate for their situations. For example, the security steps needed at a one-practitioner office will be very different from those needed at a large hospital system or chain pharmacy system. The DEA rule being issued here is consistent with HIPAA security guidance issued by HHS, as explained later in this document.

Because both DEA and HHS are involved in addressing electronic prescriptions, they held a joint public meeting on July 11 and 12, 2006, to gather information from the regulated community (practitioners and pharmacies) as well as from the prescription and pharmacy service providers, technical experts, and Federal, State, and local law enforcement. The meeting record is available at *http://www.deadiversion.usdoj.gov/ecomm/e_rx/mtgs/july2006/index.html*.

Based on the meeting and on the requirements of the CSA and the other applicable provisions of law outlined above, DEA has developed this proposed rule. As the proposed rule illustrates, DEA supports the adoption of electronic prescriptions for controlled substances in a manner that will minimize the risk of diversion. In the absence of appropriate controls, allowing electronic prescriptions for controlled substances could exacerbate the already increasing problem of prescription controlled substance abuse

in the United States, as discussed further below. It is also essential that the rules governing the electronic prescribing of controlled substances do not undermine the ability of DEA, State, and local law enforcement to identify and prosecute those who engage in diversion.

The remainder of this preamble for the rule is organized as follows:

Section II discusses the framework of pertinent provisions of the CSA and DEA regulations to provide a context for this proposed rule.

Section III describes the current requirements for controlled substance prescriptions.

Section IV discusses the existing electronic prescription and pharmacy systems.

Section V discusses potential vulnerabilities that need to be addressed to prevent electronic prescribing from contributing to the diversion of controlled substances.

Section VI discusses alternatives considered.

Section VII discusses the risk assessment DEA conducted regarding electronic prescriptions for controlled substances.

Section VIII describes the proposed rule and the rationale for the requirements DEA is proposing to impose on prescription and pharmacy systems that create, process, and archive controlled substance prescriptions.

Section IX provides a summary of the proposed rule requirements and their current implementation status.

Section X is a section-by-section analysis of the proposed rule.

Section XI describes a system for the electronic prescribing of controlled substances that DEA is proposing specifically for use by Federal health care agencies (including the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Department of Veterans Affairs, Public Health Service, and Bureau of Prisons). These agencies would be permitted to use either system for controlled substances prescribing and dispensing.

Section XII discusses the incorporation by reference of one standard published by the National Institute of Standards and Technology.

Section XIII presents the required analyses on the economic and other impacts of the proposed rule.

II. Framework of the Pertinent Provisions of the CSA and DEA Regulations

In enacting the CSA, Congress sought to control the diversion of pharmaceutical controlled substances into illicit markets by establishing a ''closed system'' of drug distribution governing the legitimate handlers of controlled substances. H. Rep. No. 91–1444, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571–72. Under this closed system, all legitimate manufacturers, distributors, and dispensers of controlled substances must register with DEA and maintain strict accounting for all controlled substance transactions *(Id.)*.

The CSA defines ''dispense'' to include, among other things, the issuance of a prescription by a practitioner as well as the delivery of a controlled substance to a patient by a pharmacy pursuant to a prescription (21 U.S.C. 802(10)). Thus, both practitioners who prescribe controlled substances and pharmacies that fill such prescriptions must obtain a DEA registration (21 U.S.C. 822(a)(2)). The CSA definition of practitioner (21 U.S.C. 802(21)) includes, among others, physicians, dentists, veterinarians, pharmacies, and, where authorized by an appropriate State authority, physician assistants and advance practice nurses.

It is important to reiterate here that DEA registers pharmacies, as opposed to pharmacists. As a rule, pharmacists themselves do not have the authority to independently prescribe controlled substances. Rather, pharmacists rely on the prescription, as written by the individual practitioner, for authority to conduct the dispensing.

Under longstanding Federal law, for a prescription for a controlled substance to be valid, it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice (*United States* v. *Moore, 423 U.S. 122 (1975)*; 21 CFR 1306.04(a)). As the DEA regulations state: ''The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.'' (21 CFR 1306.04(a)).

The CSA provides that a controlled substance in Schedule II may only be dispensed by a pharmacy pursuant to a ''written prescription,'' except in emergency situations (21 U.S.C. 829(a)). In contrast, for controlled substances in Schedules III and IV, the CSA provides that a pharmacy may dispense pursuant to a ''written or oral prescription.'' (21 U.S.C. 829(b)). Where an oral prescription is permitted by the CSA, the DEA regulations further provide that a practitioner may transmit to the pharmacy a facsimile of a written prescription in lieu of an oral prescription (21 CFR 1306.21(a)).

Enforcement of the Controlled Substances Act

The Controlled Substances Act is unique among criminal laws in that it stipulates acts pertaining to controlled substances that are permissible. That is, if the CSA does not explicitly permit an action pertaining to a controlled substance, then by its lack of explicit permissibility the act is prohibited. Violations of the Act can be civil or criminal in nature, which may result in administrative, civil, or criminal proceedings. Remedies under the Act can range from modification or revocation of DEA registration, to civil monetary penalties or imprisonment, depending on the nature, scope, and extent of the violation.

Specifically, it is unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, a controlled substance or to possess a controlled substance with the intent of manufacturing, distributing, or dispensing that controlled substance, except as authorized by the Controlled Substances Act (21 U.S.C. 841(a)(1)).

Further, it is unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, issued for a legitimate medical purpose, from a practitioner, while acting in the course of the practitioner's professional practice, or except as otherwise authorized by the CSA (21 U.S.C. 844(a)). It is unlawful for any person to knowingly or intentionally acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge (21 U.S.C. 843(a)(3)).

It is unlawful for any person knowingly or intentionally to use a DEA registration number that is fictitious, revoked, suspended, expired, or issued to another person in the course of dispensing a controlled substance, or for the purpose of acquiring or obtaining a controlled substance (21 U.S.C. 843(a)(2)).

Beyond these possession and dispensing requirements, it is unlawful for any person to refuse or negligently fail to make, keep, or furnish any record (including any record of dispensing) that is required by the CSA (21 U.S.C. 842(a)(5)). It is also unlawful to furnish any false or fraudulent material information in, or omit any information from, any record required to be made or kept (21 U.S.C. 843(a)(4)(A)).

Within the CSA's system of controls, it is the individual practitioner (e.g., physician, dentist, veterinarian, nurse

practitioner) who issues the prescription authorizing the dispensing of the controlled substance. This prescription must be issued for a legitimate medical purpose and must be issued in the usual course of professional practice. The individual practitioner is responsible for ensuring that the prescription conforms to all legal requirements. The pharmacist, acting under the authority of the DEA-registered pharmacy, has a corresponding responsibility to ensure that the prescription is valid and meets all legal requirements. The DEA-registered pharmacy does not order the dispensing. Rather, the pharmacy, and the dispensing pharmacist, merely rely on the prescription as written by the DEA-registered individual practitioner to conduct the dispensing.

Thus, a prescription is much more than the mere method of transmitting dispensing information from a practitioner to a pharmacy. The prescription serves both as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed, and as a record of the dispensing, providing the pharmacy with the legal justification and authority to dispense the medication prescribed by the practitioner. The prescription also provides a record of the actual dispensing of the controlled substance to the ultimate user (the patient) and, therefore, is critical to documenting that controlled substances held by a pharmacy have been dispensed legally. The maintenance by pharmacies of complete and accurate prescription records is an essential part of the overall CSA regulatory scheme established by Congress, wherein all those within the legitimate distribution chain must strictly account for all controlled substances on hand, as well as those received, sold, delivered, or otherwise disposed of (21 U.S.C. 827). The CSA recordkeeping requirements for prescriptions are somewhat unusual in that the practitioner is not required to maintain a record of prescriptions written; instead, the record is held only by the pharmacy.

Abuse of Controlled Substances

The level of control mandated by Congress for controlled substances far exceeds that for other prescription drugs commensurate with the facts that controlled substances can cause physical and psychological dependence and have historically been abused. Several studies of drug abuse patterns indicate that nonmedical use of prescription controlled substances (those in Schedules II through V) is an increasing problem even as the use of certain Schedule I substances appears to have declined somewhat in recent years.

The National Survey on Drug Use and Health (NSDUH) (formerly the National Household Survey on Drug Abuse) is an annual survey of the civilian, non-institutionalized, population of the United States aged 12 or older. The survey is conducted by the Office of Applied Studies, Substance Abuse and Mental Health Services Administration, of the Department of Health and Human Services. Findings from the 2006 NSDUH were released in September 2007 and are the latest year for which information is currently available.

The 2006 NSDUH [1] estimated that 20.4 million Americans were classified with substance dependence or abuse (8.3 percent of the total population aged 12 or older). Further, the 2006 NSDUH estimated that 6.7 million persons were current users, i.e., past 30 days, of psychotherapeutic drugs—pain relievers, anti-anxiety medications, stimulants, and sedatives—taken nonmedically. This represents 2.8 percent of the population aged 12 or older. Specifically, the NSDUH estimated that 5.2 million persons used pain relievers, 1.8 million used tranquilizers, 1.2 million used stimulants, and 0.4 million used sedatives. Except for tranquilizers, these estimates are increases from the corresponding estimates for 2005.

According to the NSDUH, more than 20 percent of persons age 12 or older have used psychotherapeutic drugs nonmedically in their lifetime. Overall, 33 million Americans are estimated to have used prescription pain killers for nonmedical reasons in their lifetime. Specific pain relievers with statistically significant increases in lifetime use for 18 to 25 year olds between 2003 and 2006 were the Schedule III controlled substances Vicodin®, Lortab®, or Lorcet® (from 15.0 percent to 18 percent); Schedule III controlled substances containing hydrocodone (from 16.3 percent to 19.2 percent); the Schedule II controlled substance OxyContin® (from 3.6 percent to 5.1 percent); and the Schedule II controlled substances containing oxycodone (from 8.9 percent to 10.8 percent).

Results of a separate study of seventh through twelfth grade students were released April 21, 2005, by the Partnership for a Drug-Free America. The Partnership Attitude Tracking Study [2] tracks consumers' exposure to and attitudes about drugs. The study focuses on perceived risk and social attitudes. For the first time in its seventeen-year history, the study found that teenagers are more likely to have abused a prescription pain medication to get high than they are to have experimented with a variety of illicit drugs including Ecstasy, cocaine, crack and LSD. In 2004, the study reported that nearly one in five teenagers, 18 percent, or 4.3 million teenagers nationally, indicated they have used the Schedule III controlled substance Vicodin® without a prescription. Approximately ten percent of teens, or 2.3 million teens nationally, reported using the Schedule II controlled substance OxyContin® without a prescription. Further, the study reported that ten percent, or 2.3 million teenagers nationally, reported having used prescription stimulants, Ritalin® and/or Adderall®, without a prescription. The 2005 survey indicated that 50 percent of the teenagers surveyed indicated that prescription drugs are widely available; a third indicated that they were easy to purchase over the Internet.

The 2006 National Institute of Drug Abuse survey of drug use by teens in the eighth, tenth, and twelfth grades, Monitoring the Future: National Results on Adolescent Drug Use [3], found that past-year nonmedical use of Vicodin® (Schedule III) remained high among all three grades, with nearly one in ten high school seniors using it in the past year. Despite a drop from 2005 to 2006 in past-year abuse of OxyContin® among twelfth graders (from 5.5 percent to 4.3 percent), there has been no such decline among the eighth and tenth grade students, and the rate of use among the youngest students has increased significantly since it was included in the survey in 2002.

The consequences of prescription drug abuse are seen in the data collected by the Substance Abuse and Mental Health Services Administration on emergency room visits. In the latest data, Drug Abuse Warning Network (DAWN), 2005: National Estimates of Drug-Related Emergency Department Visits,[4] SAMHSA estimates that about

[1] Substance Abuse and Mental Health Services Administration. (2007). *Results From the 2006 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H–32, DHHS Publication No. SMA 07–4293). Rockville, MD. *http://www.oas.samhsa.gov/nhsda.htm.*

[2] Partnership for a Drug-Free America; Partnership Attitude Tracking study, 2005; *http://www.drugfree.org/Portal/DrugIssue/Research/.*

[3] Johnston, L. D., O'Malley, P. M., Bachman, J. G., and Schulenberg, J. E. (2007). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2006.* (NIH Publication No. 07–6202). Bethesda, MD: National Institute on Drug Abuse; *http://www.monitoringthefuture.org/pubs.html.*

[4] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Drug*

Continued

599,000 emergency department visits involved nonmedical use of prescription or over-the-counter drugs or dietary supplements, a 21 percent increase over 2004. Of the 599,000 visits, 172,000 involved benzodiazepines (Schedule IV) and 196,000 involved opiates (Schedule II and III). Overall, controlled substances represented 66 percent of the estimated emergency department visits. Between 2004 and 2005, the number of visits involving opiates increased 24 percent and the number involving benzodiazepines increased 19 percent. About a third (200,000) of all visits involving nonmedical use of pharmaceuticals resulted in admission to the hospital; about 66,000 of those individuals were admitted to critical care units; 1,365 of the visits ended with the death of the patient. More than half of the visits involved patients 35 and older.

Means by Which Controlled Substances Are Diverted

Understanding the means by which controlled substances are diverted is critical to determining appropriate regulatory controls. Diversion of prescription controlled substances can occur in a number of ways, including, but not limited to, the following:

- Prescription pads are stolen from practitioners' offices by patients, staff, or others and illegitimate prescriptions are written.
- Legitimate prescriptions are altered to obtain additional amounts of legitimately prescribed controlled substances.
- Drug-seeking patients may falsify symptoms and/or obtain multiple prescriptions from different practitioners for their own use or for resale. In some cases, organized groups visit practitioners with fake symptoms to obtain prescriptions, which are filled and resold. Some patients resell their legitimately obtained drugs to earn extra money.
- Prescription pads containing legitimate practitioner information (e.g., name, address, DEA registration number) are printed with a different call back number that is answered by an accomplice to verify the prescription.
- Computers and scanning or copying equipment are used to create prescriptions for nonexistent practitioners or to copy legitimate practitioners' prescriptions.
- Pharmacies and other locations where controlled substances are stored are robbed or burglarized.

Diversion from within the practitioner's practice or pharmacy may also occur, such as in the following situations:

- Prescriptions are written for other than a legitimate medical purpose. Some practitioners knowingly write prescriptions for nonmedical purposes. Criminal organizations commonly referred to as ''rogue Internet pharmacies'' often employ practitioners to issue prescriptions based on online questionnaires from patients with whom the practitioner has no legitimate medical relationship.
- Controlled substances are stolen from a pharmacy by pharmacy personnel. Legitimately dispensed prescriptions may be altered to make the thefts less detectable.
- Legitimate prescriptions may be stolen from legitimate patients. The stolen legitimate prescriptions may be filled by persons addicted to or abusing controlled substances.

Given these common methods of diversion, as well as the alarmingly increasing extent of prescription controlled substance abuse in the United States, many of those at the DEA/HHS public meeting in 2006, particularly representatives of Federal and state law enforcement and regulatory agencies, emphasized that any system allowing the electronic prescribing of controlled substances must have sufficient safeguards to prevent contributing further to the diversion problem in this country. Indeed, this is true regardless of the means used to divert controlled substances in the paper-based system, because electronic prescribing of controlled substances could, if not properly implemented, present another means of diversion in addition to those listed above. However, with proper controls, the risk of diversion can actually be reduced through the use of electronic prescriptions. Among the essential elements of such a system are ensuring that only DEA registrants electronically sign and authorize controlled substance prescriptions and that the prescription record cannot be altered without the alteration being detectable. A system that fails to provide verification of the signer's identity and authority to issue controlled substance prescriptions, and/or fails to ensure that alteration of the record is detectable, would create new routes of diversion that could be even harder to prevent and detect.

III. Current Requirements for Prescriptions for Controlled Substances

As noted above, the CSA requires that, except in limited emergency circumstances, a pharmacist may only dispense a Schedule II controlled substance pursuant to a written prescription from a practitioner (21 U.S.C. 829(a)). For Schedule III and IV controlled substances, a pharmacist may dispense the controlled substance pursuant to a written or oral prescription from a practitioner (21 U.S.C. 829(b)). Every written prescription must be signed by the practitioner in the same way the practitioner would sign a check or other legal document, e.g., ''John H. Smith'' or ''J.H. Smith'' (21 CFR 1306.05). A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe by the State in which he is licensed to practice and is registered, or exempted from registration, with DEA (21 U.S.C. 822, 823). To be valid, a prescription must be written for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice; a corresponding responsibility rests with the pharmacist who fills the prescription (21 CFR 1306.04). An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of the Controlled Substances Act, and the person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Longstanding DEA regulations specify that each controlled substance prescription contain certain information including the practitioner's manual signature (21 CFR 1306.05). The manual signature affixed to the controlled substance prescription by the practitioner serves as formal attestation by the practitioner that the prescription has been written for a legitimate medical purpose and affirms the practitioner's authority to prescribe the controlled substance in question. The prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. Further, a corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by DEA regulations (21 CFR 1306.05).

A prescription may be filled only by a pharmacist acting in the usual course of professional practice who is

Abuse Warning Network, 2005: National Estimates of Drug-Related Emergency Department Visits. DAWN Series D–29, DHHS Publication No. (SMA) 07–4256, Rockville, MD, 2007; *http://dawninfo.samhsa.gov/pubs/edpubs/default.asp.*

employed in a registered pharmacy (21 CFR 1306.06). Except under limited circumstances, a pharmacist may dispense a Schedule II controlled substance only upon receipt of the original written prescription manually signed by the practitioner (21 U.S.C. 829, 21 CFR 1306.11). A pharmacist may dispense a Schedule III or IV controlled substance only pursuant to a written and manually signed prescription from an individual practitioner, which is presented directly or transmitted via facsimile to the pharmacist, or an oral prescription, which the pharmacist promptly reduces to writing containing all of the information required to be in a prescription, except the signature of the practitioner (21 U.S.C. 829, 21 CFR 1306.21).

Every prescription must be initialed and dated by the pharmacist filling the prescription (21 CFR 1304.22(c)). Under many circumstances, pharmacists are required to note certain specific information regarding dispensing on the prescription or recorded in a separate document referencing the prescription before the prescription is placed in the pharmacy's prescription records.

DEA requires the registered pharmacy to maintain records of each dispensing for two years from the date of dispensing of the controlled substance (21 U.S.C. 827(b), 21 CFR 1304.04). However, many States require that these records be maintained for longer periods of time. These records must be made available for inspection and copying by authorized employees of DEA (21 U.S.C. 827(b)). This system of records is unique in that the prescribing practitioner creates the prescription, but the dispensing pharmacy retains the record.

The signature requirement for written prescriptions for controlled substances provides DEA with reliable evidence needed to enforce the CSA in administrative, civil, and criminal legal proceedings. In criminal proceedings for violations of the CSA, the Government must prove the violation beyond a reasonable doubt. As the agency responsible for monitoring compliance with the regulatory requirements of the CSA, it is essential that DEA have the ability to determine whether a given prescription for a controlled substance was, in fact, signed by the practitioner whose name appears on the prescription. It is likewise essential that DEA have the ability to determine that a prescription that has been filled by a pharmacy was not altered after it was prepared by the practitioner. Further, because DEA relies on the records of these prescriptions in the conduct of investigations, DEA must also know that the prescription has not been altered after receipt by the pharmacy.

The elements of the prescription that identify the practitioner (the practitioner's name, address, DEA registration number, and signature) also serve to enable the pharmacy to authenticate the prescription. If a pharmacy is unfamiliar with the practitioner, it can use the registration number to verify the identity of the practitioner through publicly available records. Those same records would indicate to the pharmacy whether the practitioner has the authority to prescribe the schedule of the controlled substance in question.

Requiring that the original documents be maintained in paper form serves to support both the accuracy and integrity of each record and, thus, the accuracy and integrity of the system of records as a whole. The availability of the original written and manually signed prescription provides a level of document integrity and provides physical evidence if the record has been altered: alterations of a hard-copy record are usually apparent upon close examination. A forensic examination of a prescription can prove that a practitioner signed it or, equally important, that the practitioner did not sign it. The maintenance of the paper record at a pharmacy also ensures that State and local law enforcement agencies have access to records they need for investigations. In addition, there will be a limited number of pharmacy employees who will have annotated the record and can testify that the prescription is, in fact, the prescription they received and dispensed.

IV. Existing Electronic Prescription Systems

At present, there are more than 110 service providers that offer systems to generate electronic prescriptions and approximately 20 that handle the receipt of prescriptions at pharmacies.[5] The electronic capabilities of practitioners' offices and pharmacies and the systems used are considerably different. Both types of systems, however, can be classified in the same ways. Systems may be stand-alone software that only handle prescriptions or integrated into larger management systems. In general, pharmacy systems are part of larger pharmacy management systems. Most electronic prescription systems are now integrated into larger electronic health records (EHR) systems; existing stand-alone systems may be integrated into EHR systems in the future.[6] [7]

Systems may also be installed on a practice or pharmacy computers or may be operated by application service providers (ASPs). In the ASP model, the program is retained on the ASP servers and the user accesses the system using leased lines or over the Internet. The ASP retains the records generated. Many pharmacy systems are installed at the pharmacy, but larger chains often operate like an ASP, holding the records on a central server that any pharmacy in the chain may access. Many practitioner stand-alone electronic prescription systems are ASPs. Because practitioners want to be able to access the system when they are out of the office, access is usually over the Internet. Practitioners log on to the system using the same kinds of identification mechanisms as other online business sites (passwords, user IDs).

Pharmacy Systems. Almost all pharmacies have computerized prescription records, which are integrated into overall pharmacy management systems that process insurance claims and billings. When a pharmacy receives a prescription on paper or by phone, the pharmacist or technician keys the information on the prescription into the system; if the patient has had other prescriptions filled at that pharmacy, the patient's personal identifying information is already in the system and does not have to be rekeyed.

Many pharmacy systems have been reprogrammed to be able to capture the data from electronic prescriptions directly. Although many pharmacies have the ability to accept electronic prescriptions, few such prescriptions are sent currently. Many of the ''electronic prescriptions'' generated are in fact transmitted to the pharmacy as faxes or simply printed out and given to

[5] Estimates are based on the number of systems certified by SureScripts plus the number of electronic medical record systems certified by the Certification Commission for Health Information Technology.

[6] National Alliance on Health Information Technology, ''Report to the office of the National Coordinator on Health Information Technology on Defining Key Health Information Technology Terms'', April 28, 2008. *http://www.nahit.org/cms/images/docs/hittermsfinalreport_051508.pdf.*

[7] The National Alliance for Health Information Technology has defined the terms ''electronic Medical record (EMR),'' ''electronic health record (EHR),'' and ''personal health record (PHR).'' Both EMRs and EHRs are defined to be maintained by practitioners, whereas a PHR is defined to be maintained by the individual patient. The main distinction between an EMR and an EHR is the EHR's ability to exchange information interoperably. DEA's use of the term EHR in this rule relates to those records maintained by practitioners, as opposed to a PHR maintained by an individual patient, regardless of how those records are maintained.

the patient. Renewals are more likely to be handled electronically than original prescriptions. Nonetheless, the capability to accept electronic prescriptions is widespread in the pharmacy sector.

Practitioner Electronic Prescription Systems. Electronic prescription systems for practitioners have existed for a number of years, but are still not widely used. A Centers for Disease Control and Prevention (CDC) study of electronic medical record (EMR) system use in 2006 found that about 12 percent of physicians have the ability to send prescriptions electronically using their EMR system.[8] The number of those systems that are used or that generate true electronic prescriptions is unclear. A Rand Health study of 58 electronic prescribing systems found that only 58 percent allowed electronic transmission of the prescriptions (as a data file), while almost all produced printed prescriptions and most could generate faxes.[9] The CDC study indicated that the electronic prescribing function is one of the less used functions of EMRs.

As noted above, many electronic prescription systems are Web-based ASPs. The ASP maintains the records, which reduces the initial cost to the practice by limiting the investment in hardware and connections. The ASP enrolls a practice, issues keys or sets up other authentication mechanisms, which allow the practitioner to log onto the system from any location. Most ASP systems and some installed systems can be accessed using PDAs and other handheld devices. Because many office staff may need to access the systems, many service providers also set different levels of authority so that only practitioners may sign prescriptions; the ability to support varying access levels is a requirement for EHR certification for systems certified by the Certification Commission for Healthcare Information Technology (CCHIT). Over the long term, it is generally assumed that stand-alone electronic prescription systems will be integrated into or replaced by electronic health record (EHR) systems. In this way, data on prescriptions will be automatically added to a patient's records. This shift to EHRs is occurring rapidly. Of the 119 systems certified by SureScripts or CCHIT at the end of 2007, 103 were EHRs. DEA welcomes comments on the protections currently implemented in the systems referenced above to protect against noncontrolled substance prescription forgery, fraud, and other related crimes, and what risk-mitigating controls are in place.

DEA also seeks comment as to whether up-to-date information or statistics are available regarding physicians' ability to send noncontrolled substance prescriptions electronically using their EHR systems and usage of such system functionality. When providing comments regarding this or any other request in this NPRM, commenters should clearly cite the source of the information, the origin of the data, the methodology or analytical techniques used to derive the information, and the limitations of the information, so that DEA may determine the quality, objectivity, utility, and integrity of any data or information provided.

Intermediaries. With so many electronic prescription systems and pharmacy systems, the issue of interoperability is critical. Electronic prescriptions will be of limited value to pharmacies if their systems cannot read the prescription and translate the data directly into their databases. To deal with this issue, the National Council for Prescription Drug Programs (NCPDP) has established a standard format for prescriptions, NCPDP SCRIPT standard in XML (current version is 10, but version 8.1 is the standard that Medicare specifies). Despite the standard, interoperability problems are likely to continue as both practitioner and pharmacy systems may be using different platforms and different versions of SCRIPT. At present, the interoperability problem is solved by using intermediaries that reformat the prescription so that the receiving pharmacy will be able to process it electronically.

Electronic prescriptions are transmitted through not one, but a series of intermediaries. The first recipient, once the prescription is signed, may be the ASP or an aggregator that the electronic prescription system uses. This recipient assigns a trace number to the electronic prescription that becomes part of the prescription record. The ASP or aggregator generally will transmit it to SureScripts or a similar intermediary. SureScripts is a service established by the pharmacy industry to reformat the prescriptions so the receiving pharmacy's system can process them without rekeying the information. SureScripts certifies both pharmacy and practitioner service providers, to ensure that the data it receives will be translatable into other formats. SureScripts may transmit the reformatted electronic prescription directly to a pharmacy, the central server of a chain pharmacy, or the ASP pharmacy management system, which then routes the prescription to the pharmacy for ultimate dispensing. DEA welcomes comments on the protections currently implemented by intermediaries to protect against noncontrolled substance prescription forgery, fraud, and other related crimes, and what risk-mitigating controls are in place. DEA also welcomes comments regarding the current standards and practices used by network intermediaries to route noncontrolled substance electronic prescriptions and whether such networks allow or provide the capability to ''open'' an electronic prescription that is en route.

Hospitals. A final complexity to the electronic prescription network arises from practitioners who serve on the staff of hospitals. Two technical issues exist with any electronic prescriptions these practitioners may write. First, hospital electronic record systems are written in computer languages other than SCRIPT, often HL7. If a staff practitioner writes an electronic prescription for a patient to fill at a pharmacy outside of the hospital, the intermediaries or pharmacies have to be able to translate the electronic prescriptions from HL7 to their own computer system language. Second, staff practitioners are not required to register with DEA. They are allowed to issue prescriptions under the hospital DEA registration number with a hospital-assigned extension that identifies the specific person issuing the prescription. DEA does not dictate the format of the extension. In at least some cases, pharmacy computer systems have not been able to handle the extensions.

V. Potential Vulnerabilities That Need To Be Addressed To Prevent Electronic Prescribing From Contributing to the Diversion of Controlled Substances

Many parties in the healthcare industry are encouraging the adoption of electronic prescriptions because such prescriptions have the potential to improve patient safety by eliminating medical errors that arise from misread or misunderstood prescriptions and eliminating adverse events that result from drug interactions. They can also control costs by ensuring that more drugs prescribed are covered by formularies or are generic versions.

Although DEA also supports electronic prescribing, the Administration faces some challenges as it moves into an electronic world. A recent study conducted for HHS by the

[8] Centers for Disease Control and Prevention, ''Electronic Medical Record Use by Office-Based Physicians and Their Practices: United States 2006.'' *Advance Data from Vital and Health Statistics*, Number 393, October 26, 2007.

[9] Wang, C. Jason *et al.*, ''Functional Characteristics of Commercial Ambulatory Electronic Prescribing Systems: A Field Study,'' *Journal of the American Medical Informatics Association*, 2005; 12:346–356.

American Health Information Management Association [10] noted that ''e-prescribing presents a new vulnerability because of the increased velocity of authenticated automated transactions.'' Unless an electronic prescription system is properly designed, DEA's ability to prevent diversion and take legal action against those who violate the CSA could be seriously undermined.

As discussed above, with the paper-based system, the paper records provide DEA and other law enforcement agencies with documents that can be used in legal actions to prove that a practitioner has issued prescriptions for other than legitimate medical purposes, that others have forged prescriptions, or that pharmacy records or inventories are inconsistent with prescriptions received. The necessity for presenting prescriptions to pharmacies and picking up the drugs also limits the scope of diversion when it occurs. In contrast, electronic prescriptions can be easy to create, transmit, and alter, often without leaving a trail that links the person forging or altering a prescription to the record. Not only practice and pharmacy staff, but also staff at any of the systems involved in creating, transmitting, and processing prescriptions could generate or alter prescriptions. With the Internet and mail order pharmacies, those bent on diversion gain the ability to send prescriptions to a large number of pharmacies with a few keystrokes.

DEA's concerns with the existing electronic prescription system are the following:

- Service providers do not always determine whether the people enrolling are legally permitted to issue prescriptions, let alone controlled substance prescriptions. Some service providers appear to enroll practices over the Internet; some require submission of copies of the person's DEA registration and State license. Such procedures provide no assurance that authority to issue controlled substance electronic prescriptions will not be granted to people who are not DEA registrants. The DEA registrant list, including DEA registration numbers, is publicly available. The DEA number also appears on each controlled substance prescription and in many cases is preprinted on prescription pads so that any patient receiving a prescription for any drug, regardless of whether it is a controlled substance, will have access to the number. State license information is readily accessible from online State databases. Office staff may have access to the originals to copy. Copies of registration and license certificates would be easy to generate and submit. Present service provider procedures do not protect a practitioner from someone inside or outside the practitioner's practice setting up an account and creating fraudulent prescriptions in the practitioner's name. Moreover, current system designs could also allow a practitioner to repudiate prescriptions written for the purpose of diversion.
- Some systems may not limit who within a medical practice can ''sign'' prescriptions. Many staff at practices may have legitimate needs to access the system; only some have a legal right to sign prescriptions. Unless systems limit the ''signing'' function to practitioners with a legal right to issue prescriptions and provide unique identifiers that make it possible to determine who signed the prescription, taking enforcement action against practitioners who issue illegal prescriptions will be impossible because DEA will not be able to prove beyond a reasonable doubt who signed the prescription. This problem is exacerbated because ''signing'' in an electronic prescription system is a function that is usually nothing more than a keystroke that indicates that the prescription is complete; there is no ''signature'' applied to the prescription. In some cases, there may not be a ''signing'' function, but simply a command to transmit. (The SCRIPT standard does not currently provide a field for an electronic signature or an indication that the prescription has been signed.)
- Access to systems is usually by means of easily shared or stolen information (passwords, user IDs). As William Winsley, Executive Director of the Ohio Board of Pharmacy testified at the DEA/HHS July 2006 public meeting, ''Passwords are useless as a means of computer security in a healthcare setting.'' Too many people are in the vicinity of computers in practice offices to be certain that a password has not been compromised. If passwords or PINs are the only means of authentication for an electronic prescription system, law enforcement agencies will not be able to prove beyond a reasonable doubt who signed an electronic prescription. Practitioners will be able to repudiate prescriptions by saying that someone must have used their passwords.
- Once created and signed, electronic prescriptions pass through several intermediaries, all of which may open the record. Although this process is usually handled without individuals accessing the record, there is no guarantee that they could not do so. Most identity theft occurs not from people hacking into systems, but rather from insiders who know how to manipulate the system. Paul Donfried of SAFE BioPharma [11] and Strategic Identity Group noted at the July 2006, DEA/HHS public meeting: ''It generally is not the cryptography or the firewalls or the audit logs or the data centers that people attack. It is whatever the weak link in the chain is, which normally is the human beings who are responsible for keeping the stuff running and operating correctly.''
- The processing of the prescriptions by multiple parties could mean that law enforcement would have to prove that none of the parties altered the document. This requirement could substantially increase the cost of bringing cases against registrants who are diverting controlled substances as well as burden the service providers and intermediaries, which would have to produce audit trail records and experts to testify.
- The records of the prescriptions are often held by the service providers and intermediaries, not the pharmacies. With paper records, DEA and other law enforcement agencies have the right to inspect and remove records from pharmacies. With electronic records held by service providers and others, DEA and other agencies would have to subpoena records from the third parties—nonregistrants over whom law enforcement may have limited jurisdiction. Although this is a lesser problem for DEA, it could pose a substantial barrier to State and local law enforcement, which would be in the position of having to find other agencies willing to serve subpoenas on service providers who were located in other States.
- Records of electronic prescriptions at pharmacies and at intermediaries may be stored as strings of data, not as easily read text. These records must be able to be downloaded into a format that is easily read and manipulated by law enforcement.

DEA is convinced that its concerns can be addressed without creating insurmountable barriers to electronic prescribing. DEA's requirements in developing this proposed rule are the following:

- The approach must meet DEA's statutory mandates. Only DEA registrants may be granted the authority

[10] American Health Information Management Association, ''*Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities,*'' [September 2005] p. 45.

[11] SAFE BioPharma is an organization ''that created and manages the SAFE digital identity and signature standard for the pharmaceutical and healthcare industries.''

to sign controlled substance electronic prescriptions.

- The method used to authenticate a practitioner to the electronic prescribing system must ensure to the greatest extent possible that the practitioner cannot repudiate the prescription. Authentication methods that can be compromised without the practitioner being aware of the compromise are not acceptable.
- Electronic prescriptions must include all information required for paper controlled substance prescriptions.
- The prescription records must be reliable enough to be used in legal actions without having to substantially expand the number of witnesses that need to be called to verify records.
- The pharmacy system must allow annotation of the records as required for paper prescriptions and must indicate who made each annotation.
- The security systems used by any of the service providers must, to the greatest extent possible, prevent the possibility of insider creation or alteration of controlled substance prescriptions.

In addition, DEA wishes to adopt an approach that is flexible enough that future changes in technologies will not make the system obsolete or lock registrants into more expensive systems. DEA notes that its requirements do not relate to most of the functions of electronic prescribing systems. Other than requiring that the electronic prescription contain the basic information that any controlled substance prescription must contain (and that most prescriptions contain), DEA is not concerned about the format or transmission standards, or any of the added functions (formulary checks, clinical support, medication histories) available in electronic prescribing systems.

Further, as DEA notes throughout this document, the electronic prescribing of controlled substances is in addition to, not a replacement of, existing requirements for written and oral prescriptions for controlled substances. This proposed rule would provide a new option to prescribing practitioners and pharmacies. It does not change existing regulatory requirements for written and oral prescriptions for controlled substances. Prescribing practitioners will still be able to write, and manually sign, prescriptions for Schedule II, III, IV, and V controlled substances, and pharmacies will still be able to dispense controlled substances based on those written prescriptions and archive those records of dispensing.

VI. Alternatives Considered

In developing this rule, DEA considered a range of alternatives, from imposing virtually no requirements on existing systems to requiring systems using public key infrastructure. This section discusses the options considered and why DEA rejected some of them.

Allowing the use of any existing electronic prescription system without additional security. DEA considered whether to permit electronic prescribing of controlled substances using existing systems without any additional requirements. This would be the alternative most supported by service providers of existing electronic prescribing systems, as it would require no system modifications and would allow for the electronic prescribing of controlled substances as soon as a Final Rule permitting this activity became effective. Some have suggested that DEA permit the use of any existing system; if that system is used for diversion, DEA could then tighten its regulations later.

In discussing this alternative, and to understand why DEA rejected it, it first must be noted that any electronic prescribing systems currently being utilized are generally limited to noncontrolled substances as DEA regulations currently do not allow for the electronic prescribing of controlled substances.[12] Thus, any systems currently in place were not specifically tailored to the unique concerns relating to controlled substances—most notably the heightened need to prevent diversion of controlled substances as compared to noncontrolled substances. It is also important to understand the following regarding the current systems used to create, transmit, and process electronic prescriptions.

As discussed above, there are more than 100 vendors marketing systems to practitioners and about 20 marketing systems to pharmacies. These vendors range from start-ups with revenues of less than $1 million to a few very large corporations. There are at present no requirements for how these systems enroll practitioners, no requirements that they verify that the person enrolling is who he claims to be or is eligible to sign prescriptions. Some systems offer enrollment over the Internet. There are no requirements that prescriptions be signed only by someone authorized under State law to do so.

Some systems set access controls; others appear to grant general access to everyone in the office; in these systems, the prescription cannot be linked to a single practitioner. Many, perhaps most, of these systems allow access to prescription signing using nothing more than a password or a password/user ID, forms of identification that are easily compromised, especially in a healthcare setting where multiple staff use the same computers. Prescriptions could be created by anyone and signed by anyone. Some systems appear to rely on the good intentions of the practitioners' staff, a reliance that the high degree of insider medical identity theft and insider prescription forgery renders naïve at best.

There are no standards governing the security of the transmission of electronic prescribing systems currently being utilized. Therefore, while some of the intermediaries that handle prescriptions between the practitioner and pharmacy might have voluntarily implemented effective security measures, they are not legally obligated to do so and—in the absence of binding regulatory requirements—there is no way to ensure that they or others who might enter the market will have effective measures in the future. The intermediaries (up to five per transmission) are not required to keep records or audit trails although the best of them do. As ever, the weakest link can undermine the entire system. At the pharmacy, there are no requirements for audit trails or system security. Some pharmacy systems have good security practices, but others might not. Records could be created or altered without leaving a trace.

The existing system, in short, relies on the hope that vendors will employ good security practices; a few vendors may meet these, but others for simplicity or for economic reasons may choose to ignore them. The widespread reliance on simple passwords stored on computers available to any staff member undermines any claim of reasonable security controls. The existing voluntary certification bodies may help, but for transmission they only look at whether the system can interoperate with them. There is, in any case, no requirement that practitioners or pharmacies use only certified vendors; given the high costs of some certified systems, it would be surprising if some practitioners did not elect less expensive, uncertified solutions. Overall, the existing system provides no legal requirements for identity proofing, assurance of nonrepudiation, ability to authenticate the record, and record integrity. It exposes DEA registrants to the threat of

[12] DEA has granted an exception to its regulations to allow the United States Department of Veterans Affairs to conduct a pilot program involving the electronic prescribing of controlled substances using a system based on public key infrastructure (PKI) technology. PKI-based systems are discussed in greater detail later in this document.

identity theft, insider criminal activity, service provider or intermediary staff criminal activity, and potential criminal penalties for the actions of others that they will find hard to disprove. It creates a new high-speed route for widespread prescription forgery and diversion, which results in drug abuse and deaths. The idea that DEA should wait until this occurs before attempting to impose security requirements cannot be reconciled with the agency's statutory responsibilities and the magnitude of the harm to the public health and safety that would result if an insufficiently secure system were to cause an increase in diversion of controlled substances. Such an idea also fails to properly take into consideration the length of time required to change regulations.

For this alternative, the only way for the pharmacy, dispensing pharmacist, and DEA to ensure that the prescription a pharmacy received was, in fact, issued by the practitioner whose name and DEA registration number are on the prescription would be to require the pharmacy to call the practitioner and confirm each prescription. For DEA to allow a controlled substance prescription to be dispensed without this check would be to abdicate its statutorily mandated responsibilities. Although this alternative would impose the fewest burdens on service providers, it would be hugely expensive for practitioners and pharmacies, requiring up to 300 million callbacks a year. DEA has estimated the costs of this alternative, but DEA does not consider that the costs could be justified or that practitioners or pharmacies would adopt this alternative given the increased burden that it would represent.

Public Key Infrastructure. DEA considered proposing that all electronic controlled substance prescriptions be digitally signed using a digital certificate issued by a recognized Certification Authority. Under this approach, the prescription as signed and the digital signature would be sent to the pharmacy, which would be required to validate the prescription to ensure that it had not been altered after signature. This alternative would provide DEA and other law enforcement agencies with the best forensic evidence, and it would provide practitioners and pharmacies with the best protection against identity theft and forgeries, reducing their legal exposure. However, DEA has been advised that existing systems which follow the standards adopted by the Secretary of HHS pursuant to the MMA for electronic transmission of prescriptions and prescription-related information for covered Part D drugs prescribed for Part D eligible individuals are incompatible with the requirement of digitally signed prescriptions. Electronic prescriptions are processed through intermediaries that may reformat the prescriptions to ensure that the receiving pharmacy can capture the data; the reformatting makes validation of the record impossible. In addition, the intermediaries have expressed concern about incorporating the digital signature, which is usually at least 128 bits, within the current SCRIPT standard. Consequently, DEA does not consider this option to be a viable mandatory approach.

DEA considered and is proposing two options:

Electronically signed prescriptions with security controls. Under this alternative, practitioners would be required to undergo in-person identity proofing and submit documentation of that to a service provider. The identity proofing would be conducted by a DEA-registered hospital, a State licensing board, or State or local law enforcement agency. The service provider would be required to check the validity of the DEA registration and State license before issuing an authentication protocol to be used to sign controlled substance prescriptions. The authentication protocol would have to be two-factor, with one factor stored on a hard token (e.g., a PDA, a multifactor one-time-use password token, a thumb drive, a smart card). DEA would also impose certain system requirements related to the prescription elements and their presentation; most existing systems may already meet these requirements. The prescription would have to be transmitted immediately upon being signed and the service provider would have to digitally sign and archive the record before transmitting the plain text prescription to the intermediaries. The pharmacy would have to digitally sign and archive the prescription as received. The pharmacy system would need an internal audit trail to record any attempts to alter a record and conduct internal checks for such attempts. Both the electronic prescription service provider and the pharmacy system provider would need to obtain annual third-party audits for security and processing integrity. The service provider would have to generate a monthly log, which practitioners would be required to check for obvious anomalies. The rationale for each of the requirements is presented under the discussion of the proposed rule below.

Modified digitally signed prescriptions. Due to the current use of digital signatures by Federal health care systems, and the added security afforded by such signatures, DEA is proposing to allow practitioners that prescribe controlled substances at Federal health care facilities (e.g., Department of Veterans Affairs, Department of Defense) the additional option of using digital certificates, issued by such Federal agencies, to sign controlled substance prescriptions issued in the course of their official duties within those facilities. These Federal agencies would need to determine that the practitioner is authorized and registered, or exempted from the requirement of registration, to prescribe controlled substances. The private key would be required to be stored on a hard token. Federal agencies will already be meeting this requirement in issuing Personal Identification Verification (PIV) cards under Federal Information Processing Standard 201. Most of the system requirements would be the same as in the previous option except that the Federal agency could elect to allow the practitioner to digitally sign and archive the prescription once the DEA-required elements are complete and transmit later when other information has been added (e.g., retail pharmacy URL). The Federal agency would not have to digitally sign the record as transmitted. The pharmacy requirements would be the same. The digital signature would not be transmitted to the pharmacy; the pharmacy would not have to validate the record. However, if a Federal agency wished to include the digital signature as part of the transmission, DEA is permitting this alternative. In that case, the pharmacy would be required to validate the digital signature, but would not be required to digitally sign the prescription as received. Because a Certification Authority would issue the digital certificate and because record integrity is more assured with a digital signature, DEA would not require a check of a monthly log or third-party audits for security. The rationale for each of the requirements is presented under the discussion of the proposed rule below.

VII. Risk Assessment of Electronic Prescriptions for Controlled Substances

On December 16, 2003, the Office of Management and Budget (OMB) issued guidance to Federal agencies on e-authentication (M–04–04) that directed agencies to conduct e-authentication risk assessments to determine the level of authentication needed. It should be noted that M–04–04 was primarily intended to provide guidance to Federal agencies that utilize services through

the Internet, not private sector entities that do so. However, M–04–04 states: ''Private-sector organizations and state, local, and tribal governments whose electronic processes require varying levels of assurance may consider the use of these standards where appropriate.'' With this understanding, the document provides a useful illustration of how to identify and analyze the risks associated with the authentication process.

Assurance is the degree of confidence in the vetting process used to establish the identity of an individual to whom a credential was issued, the degree of confidence that the individual who uses the credential is the individual to whom the credential was issued, and the degree of confidence that a message when sent is secure. OMB established four levels of assurance:

Level 1: Little or no confidence in the asserted identity's validity.

Level 2: Some confidence in the asserted identity's validity.

Level 3: High confidence in the asserted identity's validity.

Level 4: Very high confidence in the asserted identity's validity.

M–04–04 states that to determine the appropriate level of assurance in the user's asserted identity, agencies must assess the potential risks and identify measures to minimize their impact. The document states that the risk from an authentication error is a function of two factors: (a) Potential harm or impact and (b) the likelihood of such harm or impact. The document then specifies six categories of harm that might result from an authentication error:

- Inconvenience, Distress, or Damage to Standing or Reputation
- Financial Loss
- Harm to Agency Programs or Public Interests
- Unauthorized Release of Sensitive Information
- Personal Safety
- Civil or Criminal Violations

With respect to each of these six categories, the agency must assess the potential impact as ''low,'' ''moderate,'' or ''high.'' Table 1 showsOMB's impact criteria for each category of harm.[13]

TABLE 1.—M–04–04 POTENTIAL IMPACTS OF AUTHENTICATION ERRORS

	Low impact	Moderate impact	High impact
Potential Impact of Inconvenience, Distress or Damage to Standing or Reputation.	At worst, limited short-term inconvenience, distress or embarrassment to any party.	At worst, serious short-term or limited long-term inconvenience or damage to the standing or reputation of any party.	Severe or serious long-term inconvenience, distress or damage to the standing or reputation to the party (ordinarily reserved for situations with particularly severe effects or which may affect many individuals).
Potential Impact of Financial Loss	At worst, an insignificant or inconsequential unrecoverable financial loss to any party, or at worst, an insignificant or inconsequential agency liability.	At worst, a serious unrecoverable financial loss to any party, or a serious agency liability.	Severe or catastrophic unrecoverable financial loss to any party; or severe or catastrophic agency liability.
Potential impact of harm to agency programs or public interests.	At worst, a limited adverse effect on organizational operations, assets, or public interests. Examples of limited adverse effects are: (i) mission capability degradation to the extent and duration that the organization is able to perform its primary functions with noticeably reduced effectiveness; or (ii) minor damage to organizational assets or public interests.	Examples of serious adverse effects are: (i) significant mission capability degradation to the extent and duration that the organization is able to perform its primary functions with significantly reduced effectiveness; or (ii) significant damage to organizational assets or public interests.	A severe or catastrophic adverse effect on organizational operations or assets, or public interests. Examples of severe or catastrophic effects are: (i) severe mission capability degradation or loss of [sic] to the extent and duration that the organization is unable to perform one or more of its primary functions; or (ii) major damage to organizational assets or public interests.
Potential Impact of unauthorized release of sensitive information.	At worst, a limited release of personal, U.S. government sensitive, or commercially sensitive information to unauthorized parties resulting in a loss of confidentiality with a low impact, as defined in FIPS PUB 199.	At worst, a release of personal, U.S. government sensitive, or commercially sensitive information to unauthorized parties resulting in a loss of confidentiality with a moderate impact, as defined in FIPS PUB 199.	At worst, a release of personal, U.S. government sensitive, or commercially sensitive information to unauthorized parties resulting in a loss of confidentiality with a high impact, as defined in FIPS PUB 199.
Potential Impact to Personal Safety.	At worst, minor injury not requiring medical treatment.	At worst, moderate risk of minor injury or limited risk of injury requiring medical treatment.	A risk of serious injury or death.
Potential impact of civil or criminal violations.	At worst, a risk of civil or criminal violations of a nature that would not ordinarily be subject to enforcement efforts.	At worst, a risk of civil or criminal violations that may be subject to enforcement efforts.	A risk of civil or criminal violations that are of special importance to enforcement programs.

The Memorandum then states:

Agencies should then tie the potential impact category outcomes to the authentication level, choosing the lowest level of authentication that will cover all of potential impacts identified. Thus, if five categories of potential impact are appropriate for Level 1, and one category of potential impact is appropriate for Level 2, the transaction would require a Level 2 authentication. For example, if the misuse of a user's electronic identity/credentials during

[13] Office of Management and Budget. ''E-Authentication Guidance for Federal Agencies'' M–04–04. December 16, 2003.

a medical procedure presents a risk of serious injury or death, map to the risk profile identified under Level 4, even if other consequences are minimal.

Again, with the understanding that M–04–04 was not specifically designed to be used by Federal agencies when issuing regulations governing the general public, the logic and method of analysis employed by M–04–04 nonetheless serves as a useful model for completing DEA's task of determining the appropriate level of authentication for electronic prescribing of controlled substances. (In fact, DEA is unaware of any other Government documents that provide any such particularized guidance for completing this task.) For the proposed rule, the two aspects that are relevant to the e-authentication risk assessment are the identity-proofing and the storage of the authentication protocol or digital certificate. The following table presents the six categories of harm and impact using the three OMB-defined potential impact values to determine an identity authentication assurance level for the electronic prescribing of controlled substances (see Attachment A of the memorandum, ''E-Authentication Guidance for Federal Agencies'').

TABLE 2.—IMPACT OF HARMS OF ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

Potential impact of authentication errors	DEA rating, OMB description	Comment
Inconvenience, Distress, or Damage to Standing or Reputation.	Moderate—At worst, serious short term or limited long-term inconvenience, distress, or damage to the standing or reputation of any party.	Identity theft, issuing of illegitimate prescriptions in a practitioner's name, or alteration of prescriptions could expose practitioners to legal difficulties and force them to prove that they had not enrolled in an electronic prescription system or issued specific prescriptions.
Financial Loss	N/A	
Harm to Agency Programs or Public Interests.	High—A severe or catastrophic adverse effect on organizational operations or assets, or public interests. Examples of severe or catastrophic effects are: (i) Severe mission capability degradation or loss of (sic) to the extent and duration that the organization is unable to perform one or more of its primary functions; or (ii) major damage to organizational assets or public interests.	Not to place such strict requirements on authentication protocols used to sign electronic controlled substances prescriptions would open the electronic prescribing system for controlled substances to rampant diversion—diversion which would be very difficult for DEA to detect because of the breadth of the potential problem. Were the authentication protocol of a practitioner compromised, and were controlled substances prescriptions to be diverted for illicit purposes based on that compromised authentication protocol, such diversion would undermine the effectiveness of prescription laws and regulations of the United States. This diversion would, by its very nature, harm the public health and safety, as any illicit drug use does. Such diversion would undermine the effectiveness of the entire closed system of distribution of the United States created by the CSA and supported by international treaty obligations.
Unauthorized release of Sensitive Information.	N/A	
Personal Safety	High—A risk of serious injury or death.	Congress expressly declared in enacting the CSA that the ''improper use of controlled substances [has] a substantial and detrimental effect on the health and general welfare of the American people.'' (21 U.S.C. 801(2)). Diversion and abuse of controlled substances results in a large number of deaths and medical visits each year; facilitating diversion can be expected to increase the level of abuse and harm.

TABLE 2.—IMPACT OF HARMS OF ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES—Continued

Potential impact of authentication errors	DEA rating, OMB description	Comment
Civil or Criminal Violations	High—A risk of civil or criminal violations that are of special importance to enforcement programs.	Given the framework of the CSA and DEA's core mission to enforce the Act, there is perhaps nothing of greater importance among DEA's administrative responsibilities than ensuring that controlled substances are dispensed only by registered practitioners. The illicit possession of legitimate (pharmaceutical) controlled substances is a violation of the CSA. The writing of a controlled substance prescription by a person not authorized to do so constitutes illegal distribution of controlled substances and is a violation under 21 U.S.C. 841(a)(1). The person writing an illegitimate prescription could be criminally prosecuted; penalties for such a conviction could include imprisonment and/or fines. Because of the number of persons having access to an electronic prescription between the time it is written and the time it is dispensed, including the practitioner's office staff, intermediaries who process the prescription, and the pharmacy staff, the potential for alteration is great. A practitioner whose prescriptions were altered by someone else—office staff or staff at one of the intermediaries—could be subject to legal action in which the practitioner would have to prove that he was not responsible for the prescriptions to avoid civil or criminal liability. If a pharmacy knowingly dispenses a forged or altered prescription, such dispensing constitutes illegal distribution and is a violation of the CSA. The pharmacy could be subject to administrative, civil, or criminal action under the CSA. A criminal conviction for unlawful dispensing in violation of the CSA is a felony that could, depending on the schedule of the controlled substance involved, and the harm resulting, result in a sentence of a lengthy period of incarceration and substantial fine. Even without a criminal conviction, civil violations of the CSA can result in substantial fines. Criminal or civil violations of the CSA might also result in revocation of the pharmacy's registration to dispense controlled substances.

DEA welcomes comments regarding its assessment of risk for the six categories of harm for the electronic prescribing of controlled substances. Commenters should frame their comments in the context of the impacts of those categories of harm included in OMB M–04–04 and Table 1 above.

OMB provides the following guidance in M–04–04 on applying the risk assessment to assurance levels.

TABLE 3.—MAXIMUM POTENTIAL IMPACTS FOR EACH ASSURANCE LEVEL

	Level 1	Level 2	Level 3	Level 4
Potential Impact of Inconvenience, Distress, or Damage to Standing or Reputation.	Low Impact	Moderate Impact	Moderate Impact	High Impact.
Potential Impact of Financial Loss	Low Impact	Moderate Impact	Moderate Impact	High Impact.
Potential impact of harm to agency programs or public interests.	n/a	Low Impact	Moderate Impact	High Impact.
Potential Impact of unauthorized release of sensitive information.	n/a	Low Impact	Moderate Impact	High Impact.
Potential Impact to Personal Safety	n/a	n/a	Low Impact	Moderate Impact.
Potential impact of civil or criminal violations	n/a	Low Impact	Moderate Impact	High Impact.

The table below shows the potential impact as rated by DEA and the assurance level associated with each.

TABLE 4.—POTENTIAL IMPACT AND ASSOCIATED ASSURANCE LEVELS FOR ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

Potential impact—DEA rating	Level of assurance
Inconvenience, Distress, or Damage to Standing or Reputation—Moderate.	Level 2.
Financial Loss—N/A	N/A.
Harm to Agency Programs or Public Interests—High.	Level 4.

TABLE 4.—POTENTIAL IMPACT AND ASSOCIATED ASSURANCE LEVELS FOR ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES—Continued

Potential impact—DEA rating	Level of assurance
Unauthorized release of Sensitive Information—N/A.	Level 1.
Personal Safety—High	Level 4.
Civil or Criminal Violations—High	Level 4.

If any one or more of the potential impact categories for authentication errors is found to be high, M–04–04 directs agencies that the appropriate assurance level must be ''Level 4'' (the highest level). Indeed, DEA notes that M–04–04 specifically lists the following as an example of a situation for which Level 4 is appropriate:

> A Department of Veteran's Affairs pharmacist dispenses a controlled drug. She would need full assurance that a qualified doctor prescribed it. She is criminally liable for any failure to validate the prescription and dispense the correct drug in the prescribed amount.[14]

The explanation provided in the above example is no less applicable where the pharmacist is employed by the private sector. Even if such risk is essentially identical for both VA pharmacies and private sector pharmacies, the reasoning of M–04–04 indicates that Level 4 assurance is appropriate in both scenarios.

NIST Special Publication (SP) 800–63, Electronic Authentication Guideline, provides guidance on applying the OMB assurance levels to identity proofing and authentication. Identity proofing is the process of determining whether the person being granted authorization to use a system is, in fact, the person he claims to be. Authentication refers to the method by which the person is then granted access to a computer system (e.g., PINs, passwords, biometrics). NIST SP 800–63 defines the steps needed to conduct identity proofing and establish authentication protocols for each OMB assurance level. DEA has used NIST SP 800–63 as a guideline in developing its proposed requirements.

Assurance Levels—Identity Proofing. Identity proofing is the process of uniquely identifying a person. NIST SP 800–63 specifies a number of requirements for both remote and in-person identity proofing for each assurance level.

DEA believes that in-person identity proofing is critical to the security of the electronic prescribing of controlled substances. Ensuring that only licensed and registered practitioners are granted the authority to sign electronic prescriptions for controlled substances is the first step to maintaining the overall security of the electronic prescribing system for these substances. At present, some service providers appear to allow enrollment over the Internet and only require the applicant to submit a copy of the State license and DEA registration. This type of enrollment increases the potential for identity theft and the creation of fraudulent identities of prescribing practitioners and, subsequently, the potential for issuance of forged prescriptions. DEA welcomes comment regarding the enrollment processes service providers have developed to adequately determine whether the people enrolling in such services are legally permitted to issue noncontrolled substance prescriptions and whether and how such processes prevent noncontrolled substance prescription forgery, fraud, and other related crimes.

In-person identity proofing protects individual prescribing practitioners from identity theft. That is, without in-person identity proofing, it would be very easy for anyone to claim to be an individual prescribing practitioner and gain access to electronic prescribing systems for controlled substances; the most likely documents used to demonstrate identity as a prescribing practitioner—State license and DEA registration—can be easily obtained. Persons who work with prescribing practitioners have ready access to State licenses and DEA registration certificates as those documents are often stored at the prescriber's practice location. A member of the office staff could alter a practitioner's registration certificate or merely submit a copy of a practitioner's State license and DEA registration and begin issuing illegal prescriptions without the practitioner's knowledge. As information regarding State licensure and DEA registration is publicly available, people outside the office could create fraudulent DEA registration certificates and State licenses using legitimate numbers and gain access to the system.

Unlike written prescriptions, once a fraudulent identity has been established, electronic prescribing provides little or no indication of the potential for fraud. With written prescriptions, if a person not knowledgeable of prescription-writing styles and tendencies writes or alters prescriptions, those prescriptions are likely to be noticed by a pharmacist who may scrutinize them further. In fact, if the prescription seems out of the ordinary in any way, e.g., the format is unusual, the paper is different from normal, the signature looks wrong, the directions are not in the usual format, the drug name is misspelled, the abbreviations used are not standard, or the quantity seems high, the pharmacy has a responsibility to contact the prescribing practitioner to verify the prescription before filling the prescription. With electronic prescribing, however, once an identity is established, all electronic prescriptions appear the same. Most information is selected from drop-down menus, and there is little to distinguish an electronic prescription written by a person who is not a legitimate prescribing practitioner from one that is written by an individual granted proper State and DEA authority to prescribe controlled substances.

Based on DEA's decision that in-person identity proofing is critical to the overall security of the electronic prescribing system, DEA examined NIST requirements for in-person identity proofing.

Briefly, at Level 2, in-person identity proofing requires the applicant to possess a government-issued photographic identification that confirms the address of record or nationality. Level 2 requires inspection of the photographic identification, and the recording of the applicant's address or date of birth and the number associated with the government-issued photographic identification. If the identification confirms the address of record then credentials are issued and notice is sent to that address; if the address is not confirmed, then credentials are issued in a manner that confirms the address of record.

At Level 3, in-person identity proofing requires the applicant to possess a government-issued photographic identification. Level 3 requires inspection of the photographic identification and verification, through the issuing government agency or through credit bureaus or similar databases, that the information contained in the identification (e.g., name, address, date of birth) are consistent with the application. The applicant's name, address, and date of birth are recorded. If the identification confirms the address of record then credentials are issued and notice is sent to that address; if the address is not confirmed, then credentials are issued in a manner that confirms the address of record.

At Level 4, two independent forms of photographic identification or accounts must be verified, one of which must be a government-issued photographic identification. Further, a new recording of a biometric of the applicant must be captured. The government-issued photographic identification must be verified with the issuing government agency. For any form of photographic identification, the applicant's name, address, and date of birth are recorded.

[14] Although OMB M–04–04 describes a Department of Veterans Affairs pharmacist needing ''full assurance that a *qualified doctor* prescribed [the controlled substance]'' [emphasis added], DEA recognizes that in addition to physicians, the Department of Veterans Affairs also employs dentists and certain mid-level practitioners who are authorized to prescribe controlled substances.

If the secondary form of identification is a financial account, the financial account number must be verified through record checks sufficient to identify a unique individual. The biometric is recorded to ensure that the applicant cannot repudiate the application. Credentials must be issued in a manner that confirms the address of record.

After careful examination of all levels of in-person identity proofing, DEA determined that none of the NIST levels addressed its unique needs and requirements. DEA does not believe that capturing a biometric at the time of enrollment is necessary, as is required at Level 4. Further, DEA does not believe that verification of identity through use of credit bureaus or other third-party agencies would be feasible or is necessary, as is required at Level 3, given that practitioner's State licenses and DEA registrations are also being examined. DEA believed that such requirements could be intrusive for practitioners, who might not want hospitals, State licensing boards, or law enforcement agencies—the entities DEA is proposing to permit conduct in-person identity proofing—to review sensitive personal information such as address information retained by credit bureaus. Finally, DEA did not believe that the address checks required at Level 2 were useful for the purpose served by the in-person identity proofing DEA believes it must require. DEA notes that address checks generally mean address of residence, because that is the address listed on most forms of government-issued photographic identification, whereas prescribing practitioners will receive information and authentication protocols at their offices, which are the addresses listed on the DEA registration and State licenses.

Therefore, DEA has decided to propose in-person identity proofing consistent with, but not equivalent to, Level 3, as discussed below, but not link that in-person identity proofing to any specific NIST requirements.

DEA could not identify any mitigating factors that would enable it to propose remote identity proofing. Remote identity proofing relies on record checks, which would not prevent identity theft and may be more intrusive than the simple in-person requirements DEA is proposing. Remote identity proofing also relies on mailing credentials to the address of record, which would not prevent a member of the office staff from applying for access to the electronic prescribing system for controlled substances and intercepting the confirmation. The electronic world allows for far easier identity theft and can make it more difficult to identify diversion when it occurs. In contrast, when DEA or the States have discovered identity theft in the context of paper prescriptions, they have been able to prosecute the criminal using the paper trail created by fraudulent prescriptions. The paper prescriptions can prove who wrote them and, for the innocent practitioner, who did not write them. With electronic prescriptions, identities can be stolen, used to issue a large number of prescriptions, then dropped within days, leaving few if any traces, or worse, traces that link to a practitioner who then would have to prove that he or she was an innocent victim, not a criminal.

DEA is proposing to allow DEA-registered hospitals, State licensing boards, and State or local law enforcement agencies to review the identity documents and sign, with the applicant, a letter or form that states that the applicant is who the applicant claims to be. This approach should lessen the burden on service providers and ensure that practitioners will be able to have their documents checked locally.

Assurance Level—Authentication Protocol. NIST SP 800–63 defines tokens as the means that a person wishing to gain access to an electronic system uses to authenticate their identity. In electronic authentication, the person wishing to gain access authenticates to a system or application over a network by proving that he has possession of a token. Therefore, a token must be protected.

Authentication methods are described as one-factor, two-factor, or three-factor, or as something you know, something you have, and something you are. PINs and passwords are something you know; cards such as ATM cards are something you have; biometrics (fingerprints, iris scans, hand prints) are something you are.

NIST SP 800–63 describes a single-factor token as either something the person knows, something the person has, or a biometric. Single-factor tokens include:

- Memorized secret tokens (passwords, passphrases).
- Pre-registered knowledge tokens: responses to a question known by the user (pet's name, favorite color).
- Look-up secret tokens—the user is prompted by the system to look up information stored on a physical or electronic device (the secret may be printed on a card or stored in the computer); the information looked up has been shared between the user and the system being authenticated to.
- Out of band tokens—Receipt of a secret on a physical device separate from the system being authenticated to which is then used to log onto the system (e.g., a password is sent to a cell phone; the person who possesses the cell phone uses the password to log onto the system).
- Single factor one time password (OTP) device—a hardware device that spontaneously generates one time passwords, which usually change every 60 seconds. The one time passwords are used to log onto the system.
- Single factor cryptographic device—a hardware device that uses embedded cryptographic keys; authentication occurs by proving possession of the device.

NIST discussed the vulnerability of single-factor authentication methods, specifically passwords, in Special Publication 800–32:

> The traditional method for authenticating users has been to provide them with a personal identification number or secret password, which they must use when requesting access to a particular system. Password systems can be effective if managed properly, but they seldom are. Authentication that relies solely on passwords has often failed to provide adequate protection for computer systems for a number of reasons. If users are allowed to make up their own passwords, they tend to choose ones that are easy to remember and therefore easy to guess. If passwords are generated from a random combination of characters, users often write them down because they are difficult to remember. Where password-only authentication is not adequate for an application, it is often used in combination with other security mechanisms.
>
> PINs and passwords do not provide non-repudiation, confidentiality, or integrity. If Alice wishes to authenticate to Bob using a password, Bob must also know it. Since both Alice and Bob know the password, it is difficult to prove which of them performed a particular operation.[15]

Pre-registered knowledge tokens usually have answers that may be known by other people in an office. Look-up secrets are as vulnerable as passwords in a medical practice settings. Out-of-band tokens would take more time to use. Single factor hard tokens could be borrowed or stolen and used easily. No single factor approach, therefore, would provide the assurance DEA and the practitioners need.

NIST SP 800–63 describes two-factor tokens as tokens that use two or more factors to achieve authentication. Multi-factor tokens include:

[15] National Institute of Standards and Technology. Special Publication 800–32 *Introduction to Public Key Technology and the Federal PKI Infrastructure; February 26, 2001. http://csrc.nist.gov/*

• Multi-factor software cryptographic tokens—a cryptographic key is stored on a computer and requires activation through a second factor of authentication.

• Multi-factor one time password device—a software device, (e.g., PDAs) or a hardware device (e.g., a card, thumb drive, fob), that generates one time passwords for use in authentication and requires activation through a second factor of authentication, usually a password.

• Multi-factor cryptographic hardware device—hardware device that contains a protected cryptographic key and requires activation through a second authentication factor.

As NIST points out, the use of more than one factor for authentication to a system raises the difficulty of an attacker successfully attacking a system. The more factors used, the more effort it takes to break the system to gain entry.

Briefly, at Level 2, single-factor authentication is allowed. Some combinations of single-factor authentication are still considered Level 2 (e.g., passwords plus pre-registered knowledge tokens are still rated as Level 2).

At Level 3, some combinations of single-factor tokens are acceptable (e.g., a password plus a single-factor one time password device). In addition, a multi-factor software cryptographic device is considered Level 3; this device allows for the storage of the cryptographic key on a disk (e.g., a hard drive of a personal computer).

At Level 4, only two types of tokens are acceptable—a multi-factor one time password device or a multi-factor cryptographic device that is stored on a hard token (e.g., a smart card, a thumb drive).

DEA is proposing that the authentication protocol meet Level 4, which requires two factors, one of which is stored on a hard token, which could be a PDA, a cell phone, a smart card, a thumb drive, or multi-factor one time password token. DEA has determined that only Level 4 meets its requirements based on the risk assessment and on the problems that arise with Level 3, where one of the factors can be stored on a computer rather than a hardware device that the practitioner can possess, or Level 2, where only a single factor is required. NIST describes Level 4 tokens as follows: ''To achieve Level 4 with a single token or token combination, one of the tokens needs to be usable with an authentication mechanism that strongly resists man-in-the-middle attacks—this entails an electronic interface which may be placed under access control by the Claimant's (the person seeking to gain access to the system) operating system.'' [16] [17] DEA would like public comment on the present state of multi-factor tokens as implemented through multi-function devices such as PDAs, cell phones, smart cards, thumb drives and laptop computers.

As DEA is not proposing specific controls regarding the authentication process or the transmission of the prescription information, DEA believes that the security of the authentication itself is critical to bind the practitioner to the prescribing transaction. Level 4 authentication protocols protect the practitioner from the most likely ''attack,'' the use of his password or other token to access the system and issue prescriptions. Because Level 3 allows the storage of authentication protocols on office computers, the practitioner has no assurance that his authentication protocol will be safe or that he will be aware if it is compromised. From a law enforcement perspective, an authentication protocol stored on a computer to which others have access makes linking a prescription to a practitioner or to a staff member who has illegally issued prescriptions all but impossible. Level 4, where the practitioner can retain possession of the hard token, protects the practitioner and provides law enforcement with the necessary nonrepudiation.

Because of the attributes of medical practices, DEA could identify no mitigating factors that could overcome the vulnerabilities that exist and allow a lower level of assurance. In medical practices, most staff members have access to any of the computers in the office. Practitioners and nurses see patients in multiple examination rooms, moving from room to room; of necessity, practitioners must leave their offices and computers unattended for long periods of time. Passwords, which are usually part of two-factor authentication protocols to access the system, are vulnerable to attack because (1) many people write them down; (2) most people choose passwords that are easy to guess; and (3) in medical settings, with multiple people working in the vicinity of a computer, it is easy for someone else to watch a password being keyed into the system. If both parts of a multi-factor identification protocol can be stored on an office computer, or if there is only one factor needed (Level 2), the practitioner will have no assurance that someone in the office is not issuing prescriptions in his name. The practitioner will also be able to repudiate any prescription written in his name; law enforcement officials will not be able to prove beyond a reasonable doubt in a criminal proceeding that his authentication protocol had not been compromised. Storing one of the factors on a hard token means that the practitioner can retain possession of the device and ensures that it is not misused. The practitioner will not be able to repudiate prescriptions issued in his name; the practitioner will either have written the prescription, knowingly given the hard token to someone else, or, if the token was lost, stolen, or compromised, have taken appropriate actions (such as ensuring that the authentication protocol has been revoked to prevent its misuse).

The hard token protects the practitioner in the same way a manually signed written prescription does. If a written prescription is forged, a practitioner can prove that he did not write it by comparing handwriting. By maintaining sole possession of the hard token, the practitioner can eliminate the risk of fraudulent prescriptions and, if the token is lost, stolen, or compromised, he will be immediately alerted to the threat and have the authentication protocol revoked. This assurance that only a legitimate practitioner issued the prescription also protects the pharmacy. As discussed above, with a paper prescription there are potentially many indications that the prescription was not written by a practitioner. If the prescription seems out of the ordinary in any way the pharmacy has a responsibility to verify the prescription before filling the prescription. With electronic prescriptions, it will be much more difficult to identify these potentially telltale characteristics because the software fills in items from a menu of acceptable options; unless the quantity is high, the pharmacist will have little reason to question an electronic prescription.

The requirement for two-factor authentication (something you know and something you have) has been implemented by a number of healthcare systems. One system with almost 300 hospitals and clinics is using a

[16] National Institute of Standards and Technology. Special Publication 800–63–1 *Electronic Authentication Guideline* draft; February 20, 2008. p. 52.

[17] DEA notes that in the course of drafting this rulemaking, the National Institute of Standards and Technology issued a new draft Special Publication 800–63, which revises some guidelines regarding electronic authentication. DEA has taken these new guidelines into account in drafting this Notice of Proposed Rulemaking recognizing, however, that this Special Publication is a draft and subject to revision by NIST when the final SP 800–63–1 is issued.

combination of PINs (something you know) and a one-time-password token or software tokens (PDAs) for almost 30,000 users. Another medical center uses the same approach for more than 4,500 users. A third health care system with a variety of treatment centers has deployed this approach to 8,000 people at more than 40 sites. These deployments indicate that the requirement is feasible in healthcare settings and that it is flexible enough to provide access and access control as practitioners move among settings in which they practice.

Although the electronic prescribing of controlled substances plainly fits in the categories of transactions for which Level 4 assurance is warranted, DEA has decided, following interagency discussions, not to propose all of the authentication requirements that NIST SP 800–63 indicates are appropriate for Level 4. Among other things, as explained below, DEA is not proposing that practitioners digitally sign prescriptions or that pharmacies routinely validate prescriptions that are digitally signed because doing so would be incompatible with many existing systems currently in use for the electronic prescribing of noncontrolled substances. Nonetheless, DEA is proposing here an alternative authentication system that comes as close as reasonably possible to the level of security called for in NIST SP 800–63 while remaining compatible with existing systems used for noncontrolled substance prescriptions and, at the same time, adhering to DEA's overarching obligation to minimize the likelihood of diversion of controlled substances.

Assurance Level—Authentication Process. The authentication process addresses security between the creator of a message and its recipient. At Level 4, the authentication process involves strong cryptographic authentication of all parties and all sensitive data transfers. A variety of technologies can meet Level 2 and 3; the levels are defined by their resistance to certain forms of attack. Level 2 can be met with an encrypted TLS protocol session. Level 3 can be met with authenticated TLS and public key certificates.

DEA is not proposing to set any standards for the authentication process. The NIST requirements apply primarily to the transmission of information. DEA is concerned about the possibility that an electronic prescription could be altered during transmission, but the agency is not proposing specific regulations in this area at this time. DEA is proposing to address the vulnerabilities that exist by having the prescription digitally signed by the service provider prior to transmission and on receipt at the pharmacy. These requirements will not prevent alteration during transmission, but they will allow DEA to identify that it has occurred and protects registrants from being accused of issuing a fraudulent prescription or altering a legitimate prescription. DEA also notes that the security of these records during transmission is subject to HIPAA.

Summary. In conclusion, although the risk of electronic prescribing of controlled substances maps to Assurance Level 4 using the criteria of M–04–04, DEA is not proposing all of the requirements associated with that level. Instead, DEA is proposing in-person identity proofing specific to its needs; these requirements are consistent with, but not equivalent to, Level 3, and address concerns specific to DEA. Further, DEA is proposing use of a hard token, with that hard token meeting the requirements of Level 4. Finally, DEA is not proposing any requirements regarding the authentication process and transmission of the electronic prescriptions. The table below provides a summary of DEA's conclusions regarding its risk assessment of systems to permit the electronic prescribing of controlled substances.

TABLE 5.—SUMMARY OF RISK ASSESSMENT FOR ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

M–04–04 Assurance Level	Level 4—High potential impact of harm to agency programs or public interests, personal safety, civil or criminal violations.
NIST identity proofing	In-person identity proofing requirements specific to DEA; requirements consistent with, but not equivalent to, NIST Level 3 in-person identity proofing.
NIST authentication protocol	Level 4—Use of hard token or multifactor one-time-use password token is necessary to bind the prescriber to the prescription.
NIST authentication process	N/A—DEA is not proposing any requirements in this area.

As has been discussed, DEA is proposing in-person identity proofing requirements consistent with, but not equivalent to, Level 3; authentication protocol requirements, use of a hard token and two-factor authentication, meeting the requirements of Level 4; and no requirements regarding the authentication process. DEA welcomes comments and information regarding alternative solutions for the electronic prescribing of controlled substances employing security controls that are as effective as those being proposed in this Notice of Proposed Rulemaking and also would meet DEA statutory and regulatory obligations under the Controlled Substances Act. Information provided should be as specific and detailed as possible to provide the Administration with an understanding of how the commenter believes the alternative solution could be implemented to satisfy the foregoing considerations. Any person providing such comments should discuss the specific risks being addressed and how any such risk-mitigating controls are incorporated into the alternative being discussed, and should state why the commenter believes such controls are adequate to address DEA's concerns. Any person providing such comments should also discuss the system vulnerabilities, risks, and weaknesses of any alternatives provided.

If a commenter believes that any proposed requirement is either too stringent or too lax, the commenter should so state, providing a detailed explanation of how the controls mitigate the identified risks, or how the lack of controls aggravate or fail to address the risks involved in the electronic prescribing of controlled substances and, thus, why the commenter's alternative warrants consideration as an alternative to the requirement being proposed. Hence all comments should clearly identify how all risk-mitigating compensating controls adequately address each security concern outlined in the proposed rule.

For example, DEA welcomes comments on the following topics:

- Whether in-person identity proofing requirements consistent with, but not equivalent to, Level 3, are sufficient to address DEA's concerns, or whether (a) more stringent requirements, such as those required under Level 4, are necessary, or (b) DEA's concerns could be addressed with Level 2 requirements combined with risk-mitigating controls.
- Whether authentication protocol requirements, use of a hard token and two-factor authentication, meeting the requirements of Level 4 are sufficient to

address DEA's concerns, or whether (a) more stringent requirements, such as those imposed in a public key infrastructure system, are necessary, or (b) DEA's concerns could be addressed with Level 3 requirements combined with risk-mitigating controls.

• Whether no requirements regarding the authentication process, as proposed in this rule, should cause DEA concern, such that imposing requirements is necessary.

VIII. Proposed Standards for Electronic Prescription Systems for Controlled Substances

The following discussion relates to requirements DEA is proposing regarding the creation, signature, transmission, processing and dispensing of controlled substance prescriptions. As discussed below, practitioners and pharmacies—DEA registrants—must use systems and service providers which comply with all requirements DEA may finalize. While these requirements pertain specifically to prescriptions for controlled substances, nothing in this rule precludes practitioners, pharmacies, or service providers from using these same standards for prescriptions for noncontrolled substances, if they so desire. However, DEA notes that any references throughout the following discussion relate solely to prescriptions for controlled substances.

In this rule, DEA is proposing various security requirements for systems and service providers that market software and services to practitioners and pharmacies to create, sign, transmit, process and dispense electronic controlled substance prescriptions. It is incumbent upon DEA registrants—practitioners and pharmacies—the entities regulated by DEA, to use systems and service providers that comply with DEA security requirements for the electronic prescribing and dispensing of controlled substances. DEA recognizes that its registrants may not be able to evaluate a service provider's compliance and so is establishing third-party audit and other requirements to assist registrants in determining whether a system or service provider they currently use, or are considering using, meets DEA security requirements. While this preamble and rule require actions of service providers, it is the DEA-registered practitioner or pharmacy DEA will look to if the system or service provider that practitioner is using is not in compliance with DEA regulations. It is, ultimately, the DEA-registered individual practitioner and pharmacy who are responsible for the prescribing and dispensing of any controlled substance prescription, and the requirements of this rule do not change that longstanding responsibility and liability.

DEA is proposing the following requirements for the use of electronic systems to create, sign, dispense, and archive controlled substance prescriptions, which are discussed in detail below:

• The electronic prescription service provider must receive a document prepared by an entity permitted to conduct in-person identity proofing of prescribing practitioners regarding the conduct of the in-person identity proofing. The document may be prepared on the identity proofing entity's letterhead or other official form of correspondence, or the service provider may design a form for use by the identity proofing entity. Regardless of the format, the document must contain certain information required by DEA. Entities DEA is proposing to permit conduct in-person identity proofing of prescribing practitioners include:

○ The entity within a DEA-registered hospital that has previously granted the practitioner privileges at the hospital (e.g., a hospital credentialing office);

○ The State professional or licensing board, or State controlled substances authority, that has authorized the practitioner to prescribe controlled substances;

○ A State or local law enforcement agency.

○ The service provider must check both the practitioner's State license and DEA registration to determine that both are current and in good standing.

• Authentication: Access to the electronic prescribing system for the purposes of signing prescriptions must meet the standards for Level 4 authentication in NIST SP 800–63. That is, the system must require at least two-factor authentication to access the system; one factor must be a cryptographic key stored on a hard token that meets the requirements for Level 4 authentication in NIST SP 800–63 or a multi-factor one time password token. The hard token must be a hardware device that meets the following criteria:

○ The token must require entry of a password or biometric to activate the authentication key.

○ The token is not able to export the authentication key.

○ The token must be validated under Federal Information Processing Standard (FIPS) 140–2 as follows:

■ Overall validation at Level 2 or higher.

■ Physical security at Level 3 or higher.

• The security of the system must be audited annually using a third-party audit that meets the requirements of a SysTrust or WebTrust audit for security and processing integrity.

• The system must limit signing authority to those practitioners that have a legal right to sign prescriptions for controlled substances (i.e., the system must set varying levels of access to the system based on responsibilities).

• The system must have an automatic lock out if the system is unused for more than 2 minutes.

• The prescription must contain all of the required data (date of issuance of the prescription; patient name and address; registrant full name, address, DEA registration number; drug name, dosage form, quantity prescribed, and directions for use; and any other information specific to certain controlled substances prescriptions mandated by law or DEA regulations). Prior to signing the controlled substance prescription, the system must show the prescribing practitioner at least the patient name and address, drug name, dosage unit and strength, quantity, directions for use, and the DEA number of the prescriber whose identity is being used to sign the prescription.

• Where more than one prescription has been prepared for signing, prior to authenticating to the system the practitioner must positively indicate which prescription(s) are to be signed.

• The practitioner must authenticate himself to the system immediately before signing a prescription.

• After authenticating to the system but prior to transmitting the prescription, the system must present the practitioner with a statement indicating that the practitioner understands that he is signing the prescription being transmitted. If the practitioner does not so indicate, by performing the signature function, the prescription cannot be transmitted.

• The system must transmit the electronic prescription immediately upon signature. The system must not transmit a controlled substance prescription unless it is signed by a practitioner authorized to sign such prescriptions.

• The electronic data file must include an indication that the prescription was signed.

• The system must not allow printing of prescriptions that have been transmitted; if a prescription is printed, it must not be transmitted.

• The system must generate a monthly log of controlled substance prescriptions and transmit it to the

practitioner for his review. The practitioner must indicate that the log was reviewed. A record of that indication must be maintained for five years.

- The first recipient of the prescription must digitally sign the prescription and archive the digitally signed version of the prescription as received.
- The first pharmacy system that receives the prescription must digitally sign and archive a copy of the prescription as received. Alternatively, the intermediary that transmits the prescription to the pharmacy may digitally sign the transmitted prescription and transmit both the record and the digitally signed copy for the pharmacy to archive.
- The digital signatures must meet the requirements of FIPS 180–2 and 186–2.
- The pharmacy system must check to determine whether the DEA registration of the prescribing practitioner is valid. (Alternatively, any of the intermediary systems may conduct this check provided that the record indicates that the check has been conducted. The CSA database may be cached for one week from the date of issuance by DEA of the most current database.)
- The pharmacy system must be able to store the complete DEA number including extensions.
- The pharmacy system must have an audit trail that identifies each person who annotates or alters the record. The pharmacy system must conduct daily internal audits to identify any auditable events.
- The system must have a backup system of records stored at a separate location.
- The pharmacy system must have a third-party audit that meets the requirements of SysTrust or SAS 70 audits for security and processing integrity.
- The contents of a controlled substance prescription must not be altered, other than by reformatting, during transmission.
- A prescription created electronically for a controlled substance must remain in its electronic form throughout the transmission process to the pharmacy; electronic prescriptions may not be converted to other transmission methods, e.g., facsimile, at any time during transmission.

DEA would like the public to comment on the ability of those members of industry currently providing electronic prescribing systems for noncontrolled substances to meet the requirements set forth in this proposed rule, and whether there might be entrepreneurs not currently providing electronic prescribing systems who would be willing and able to develop innovative systems that would meet the requirements proposed here.

Other Requirements

In addition to the system requirements, DEA is proposing to require the following:

- A registrant must have separate password/keys for each DEA registration he holds and uses to issue prescriptions. Multiple keys may be stored on the same hard token.
- The registrant must use the appropriate DEA registration for prescriptions issued. Practitioners holding multiple registrations in a single State may use just one for any prescription written in that State.
- The registrant must retain sole possession of the hard token. If a token is lost or compromised and the registrant fails to notify the service provider within 12 hours of discovery, the registrant will be held responsible for any prescriptions written using the token.
- The pharmacy must annotate the record with the same information required for a paper prescription.
- The practitioner and pharmacist must notify DEA and the service provider if they identify problems in the logs they review that indicate that prescriptions have been created without their knowledge or altered.

Discussion of the Proposed Rule System Requirements

As noted previously, electronic prescribing is in addition to existing prescribing methods for controlled substances. DEA's goal is to impose as few new requirements on electronic prescription systems as possible while retaining the ability to enforce the Controlled Substances Act and its implementing regulations. Many of the requirements listed above exist in at least some systems currently in use. The Certification Commission for Health Information Technology EHR certification standards for security cover many of the access and authentication requirements DEA is proposing here. DEA believes that the proposed requirements will protect both practitioners and pharmacies by ensuring that they can meet their legal obligations and lessen the threat of someone misusing their authorities to divert controlled substances. DEA emphasizes that its electronic prescription requirements do not alter the responsibilities of the practitioner and pharmacy in regard to controlled substance prescriptions. Both the prescribing practitioner and the dispensing pharmacy have a legal responsibility to ensure that only prescriptions issued for legitimate medical purposes by DEA registrants acting in the usual course of their professional practice are dispensed. A practitioner who knowingly allows someone to issue prescriptions in the practitioner's name is legally responsible for those prescriptions. A pharmacy that fails to check the validity of a controlled substance prescription before dispensing is legally responsible if the prescription is invalid.

In-person identity proofing. DEA considered requiring service providers to conduct in-person identity proofing of prescribing practitioners as part of their enrollment process. However, after careful consideration, DEA determined that in-person identity proofing by service providers created certain vulnerabilities which could not be overcome. Specifically, DEA was concerned that by requiring service providers to both identity proof practitioners and issue practitioners access to the electronic prescribing system to prescribe controlled substances, the entire system was vulnerable to compromise. Without separation of the identity and enrollment tasks, it could be quite easy for service provider staff to create a fraudulent identity and enroll that identity in the electronic prescribing system. While some service providers have asserted that their staffs are trustworthy, DEA did not want to establish a system which could be easily subverted for the diversion of controlled substances. Further, DEA was concerned that such a system may prove to be inconvenient for prescribing practitioners and service providers alike. Although DEA believes that many service providers would be on site at practitioners' offices routinely due to the complexity of the EHR systems of which electronic prescribing is often a part, DEA recognizes that conducting enrollment activities at that time may be inconvenient. Practitioners may not be at the practice location when the service provider staff is present. If enrollment could not occur, service providers' staff would have to make separate trips specifically for in-person identity proofing. Such trips could be difficult depending on the location of the service provider as compared to the practitioner.

To address DEA's concerns that the identity proofing and enrollment functions not reside within the same entity, and to ensure that practitioners have ready access to the entities

permitted to conduct in-person identity proofing, DEA is proposing that the following entities may conduct in-person identity proofing:

- The entity within a DEA-registered hospital that has previously granted that practitioner privileges at the hospital (e.g., a hospital credentialing office);
- The State professional or licensing board, or State controlled substances authority, that has authorized the practitioner to prescribe controlled substances;
- A State or local law enforcement agency.

DEA is proposing that before a service provider grants access to the electronic prescription system for the prescribing of controlled substances, the service provider must receive a document prepared by one of the above-listed entities regarding the conduct of the in-person identity proofing. DEA is proposing two alternatives for the format of the identity proofing document: The document may be prepared on the identity proofing entity's letterhead or other official form of correspondence, or the service provider may design a form for use by the identity proofing entity. Regardless of the format, the document must contain all of the following information:

- The name and DEA registration number, where applicable, of the entity which conducted the in-person identity proofing of the practitioner;
- The name of the person within the entity who conducted the in-person identity proofing of the practitioner;
- The name and address of the practitioner whose identity is being verified;
- For each State in which the practitioner wishes to prescribe controlled substances electronically, the name of the State licensing authority and State license number of the practitioner whose identity is being verified;
- Except for individual practitioners who prescribe controlled substances using the DEA registration of the institutional practitioner, for each State in which the practitioner wishes to prescribe controlled substances electronically, the DEA registration number and date of expiration of DEA registration of the practitioner whose identity is being verified;
- For individual practitioners who prescribe controlled substances using the DEA registration of the institutional practitioner, a statement by the institutional practitioner acknowledging the authority of the individual practitioner to prescribe controlled substances using the institution's DEA registration, and the specific internal code number assigned to the individual practitioner;
- The type of government-issued photographic identification checked (e.g., the practitioner's driver's license, passport) and a statement that the photograph on the identification matched the person presenting the photographic identification;
- The date on which the practitioner's in-person identity proofing was conducted;
- The signature of the person within the entity who conducted the in-person identity proofing;
- The signature of the practitioner who is the subject of the in-person identity proofing.

Before granting the practitioner access to the system to sign controlled substances prescriptions, the service provider must check with each State and DEA to determine that the practitioner's State license to practice medicine is current and in good standing. In those States in which a separate controlled substance registration is required to prescribe controlled substances, the service provider must also check with the appropriate State authority to determine that the practitioner's State license is current and in good standing. Finally, to ensure that the application to gain access to sign controlled substances is legitimate, the service provider must contact the prescribing practitioner at the practitioner's registered location by telephone to confirm the practitioner's intent to apply to prescribe controlled substances using the service provider's system. The service provider must obtain the telephone number from a public source other than the application received from the practitioner. Alternatively, the service provider may confirm the practitioner's intent in person at the practitioner's registered location.

The service provider must retain the document regarding identity proofing in its files for five years. DEA recognizes that in-person identity proofing will add a step to enrollment, but anything less would make it easy to steal a practitioner's identity and issue fraudulent prescriptions. In-person identity proofing will protect practitioners from this type of abuse. The records may be maintained electronically.

DEA seeks comments on in-person identity proofing requirements, and those requirements' effects, if any, on practitioners, including those practicing at multiple locations. DEA also seeks comments regarding alternatives to in-person identity proofing that achieve the same or higher level of assurance as that which DEA is proposing here.

Authentication. As explained above in the risk assessment, DEA is proposing that the authentication protocol must be two-factor and meet NIST SP 800–63 Level 4 criteria. One factor must be stored on a hard token that meets the FIPS 140–2 standard for the cryptographic module.

The HIPAA Security Guidance issued by HHS on December 28, 2006, also recommends two-factor authentication, beyond a combination of password and user ID, although it does not detail how this should be implemented.[18] The standards for electronic health records system security developed by the Certification Commission for Healthcare Information Technology (CCHIT) require systems to support two-factor identification.[19] Consequently, all of the EHR systems certified by CCHIT (approximately 85 systems) already support two-factor authentication. The requirement to store the key on a token will not impose an incremental cost for these systems.

The highest form of protection would be three-factor authentication (something you know, something you have, and something you are), but given the difficulties that still exist in ensuring that biometric readers function accurately at all times, DEA decided not to require a biometric password. DEA notes that biometric authentication is not prohibited in this rule; DEA supports this method of authentication, but is not requiring it at this time. Practitioners may decide to use a biometric as one of the passwords; some systems, including some PDAs, have, or support the use of, a fingerprint reader for access control.

Federal Information Processing Standard (FIPS) 140–1/140–2 is a standard entitled ''Security Requirements for Cryptographic Modules.''[20] The standard is issued by NIST to lay out general requirements for cryptographic modules for computer and telecommunications systems. These standards ensure that cryptographic modules, which protect information such as passwords and other records,

[18] HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information December 28, 2006; *http://www.cms.hhs.gov/SecurityStandard/Downloads/SecurityGuidanceforRemoteUseFinal122806.pdf.*

[19] CCHIT Security Criteria 2007 Final 16 Mar 07; criteria S21. *http://www.cchit.org/files/Ambulatory__Domain/CCHIT_Ambulatory_SECURITY_Criteria_2007_Final_16Mar07.pdf.*

[20] National Institute of Standards and Technology. FIPS 140–2 ''Security Requirements for Cryptographic Modules'', May, 2001. *http://csrc.nist.gov/publications/PubsFIPS.html.*

are robust enough that ''breaking'' the encryption is generally not feasible. The FIPS standards have been adopted by the United States government and are required for all cryptographic-based security systems that are used by, or approved by, Federal agencies to protect unclassified information. DEA, therefore, must require that the software modules used comply with these standards. A list of vendors whose cryptographic modules have been validated as FIPS 140–2 compliant may be obtained from the NIST Web site at *http://csrc.nist.gov/cryptval/140–1/1401val.htm*. As of March 2008, more than 900 modules have been certificated as compliant. The vendors include providers of PDAs, cell phones (Palm, Blackberry, Nokia), one time password tokens, as well as network and software providers. (When the FIPS 140–1 standard was updated to 140–2, all modules approved under the 140–1 standard were grandfathered and are considered compliant under 140–2.)

DEA notes that practitioners are not required to learn cryptographic keys; a password entered into a hard token accesses the key, which the service provider then recognizes. From the practitioner's perspective, the only difference from the common security controls on computer systems is that one of the keys is stored on a token. If that token is a PDA, the practitioner may not see a difference from the existing electronic prescription systems except when the practitioner wants to use a personal computer, when he would need to connect the PDA to the computer to access the system.

Authentication protocol expiration and revocation. The practitioner's authentication protocol to sign controlled substances prescriptions is based on the validity of the practitioner's DEA registration and on the security of the hard token and password. DEA would require the service provider to revoke the practitioner's authentication protocol if the practitioner's DEA registration expires (unless the service provider determines that the registration has been renewed), is revoked, suspended, or terminated. DEA will make available to service providers information regarding the registration status of prescribing practitioners, including practitioners' names, addresses, DEA registration numbers, and dates of expiration for those DEA registrations. The service provider must check the DEA registration database at least once a week to ensure that the service provider has the most current DEA registration information. DEA will permit service providers to cache this information for one week from the date of issuance by DEA of the most current database. DEA seeks comment regarding the interval for updating by DEA of registration information to service providers.

Further, DEA is proposing to require the service provider to revoke the authentication protocol used to sign controlled substance prescriptions immediately upon receiving notification from the practitioner that a password or token has been compromised, lost, or stolen. In such cases, the service provider may issue a new authentication protocol to the practitioner.

DEA is interested in receiving comment regarding the current industry practices used to authenticate practitioners who use electronic prescribing systems for noncontrolled substances and whether and how such practices prevent noncontrolled substance prescription forgery, fraud, and other related crimes.

Access limitations and signing. DEA is proposing a series of requirements related to the creation, signing, and transmitting of controlled substance prescriptions:

- After authenticating to the system but prior to signing the controlled substance prescription, the system must present the practitioner with a statement indicating that the practitioner understands he is signing the prescription being transmitted. If he does not so indicate, the prescription must not be transmitted.
- The electronic prescription system must include a function that requires a practitioner to electronically ''sign'' the completed prescription prior to transmission. The prescription file must include an indication that the prescription was signed.
- The system must limit access to the signing function for controlled substances to practitioners authorized to sign controlled substance prescriptions.
- The system must transmit the prescription immediately upon signature.
- The system must not transmit the prescription unless it has been signed.

DEA wishes to ensure that the act of signing controlled substances prescriptions is clearly understood by the practitioner. Therefore, DEA is proposing to require that, after authenticating to the system but prior to signing the controlled substance prescription, the system must present to the practitioner certain information regarding controlled substances prescriptions being transmitted. Specifically, the system must display for the practitioner the patient's name and address; the name of the drug being prescribed; the dosage strength and form, quantity, and directions for use; and the DEA registration number under which the prescription will be authorized. While this information is displayed, the practitioner must be presented with the following statement (or its substantial equivalent): ''I, the prescribing practitioner whose name and DEA registration number appear on the controlled substance prescription(s) being transmitted, have reviewed all of the prescription information listed above and have confirmed that the information for each prescription is accurate. I further declare that by transmitting the prescription(s) information, I am indicating my intent to sign and legally authorize the prescription(s).'' The practitioner must positively indicate agreement with this statement. Such agreement can be accomplished through a check box or other means determined by the system. If the practitioner does not indicate agreement to this statement, the controlled substances prescriptions may not be transmitted.

DEA believes that such a statement is necessary to help to positively bind the practitioner to the prescription. DEA believes that this requirement is similar to many banking and online billing systems that require the user to agree to certain terms and conditions before billing or other financial transactions are permitted to occur. This statement will help to provide nonrepudiation of the prescriptions; that is, the inclusion of this statement will make it more difficult for the practitioner to deny having signed the controlled substance prescriptions.

Although the requirement for signing may seem obvious, signing is not currently an automatic part of electronic prescriptions. The standard that the industry has developed and HHS has adopted for the transmission of electronic prescriptions (the National Council for Prescription Drug Programs (NCPDP) SCRIPT) does not include a field that indicates that the prescription has been signed. Signing an electronic prescription does not create a record of the act of signing; it is simply a function that usually is linked to transmission. The SCRIPT fields clearly provide for cases where someone other than the practitioner creates and transmits a prescription under the practitioner's supervision. Although this approach may be legal for prescriptions for noncontrolled substances, it is not legal for controlled substance prescriptions. Agents of a practitioner may prepare the prescription at the practitioner's direction, as they can with paper prescriptions, but only the registered

practitioner may sign and issue the prescription. As noted above, the signature represents the practitioner's attestation of the validity of the prescription and legally binds the practitioner to the prescription.

Another scenario that the SCRIPT standard allows is for two DEA registration numbers associated with two practitioners to appear on a single prescription; the standard allows a practitioner and supervisor to be identified with DEA registration numbers. This scenario is not acceptable for controlled substance prescriptions. The prescribing registrant is solely responsible for issuing the prescription; approval by a supervisor does not alter the legal liability of the prescribing practitioner for the validity of the prescription. Identifying two registrants on a prescription could lead to confusion about which registrant was legally responsible and create confusion in pharmacy record systems.

To ensure that only authorized practitioners sign controlled substance prescriptions, the service provider must ensure that only DEA-registered practitioners are allowed to sign prescriptions for controlled substances and that each practitioner is uniquely identified. Specifically, the system must require that the DEA registrant whose DEA number is listed on the prescription sign the prescription. The system must not allow any other person to sign the prescription. Many office staff may have legitimate reasons to access the system, particularly when the electronic prescription capability is part of an EHR system. Some service providers now explicitly place limits on the level of access granted to various members of a practice. CCHIT Security Criteria require that EHR systems set access controls for specific tasks. DEA would require that all service providers do this if their systems will be used to issue controlled substance prescriptions. Nurses or other members of a practice staff may prepare the prescription, as they may with paper prescriptions, but the systems must allow only a practitioner authorized by the State and DEA to issue controlled substance prescriptions to sign and transmit the prescription.

This requirement is necessary to prevent others with access to the system from creating and signing prescriptions. In a recent discussion of an electronic prescription system, the service provider indicated that the illegality of a staff member issuing a prescription was a sufficient deterrent to prevent this from happening just, the service provider stated, as it prevents staff from stealing prescription pads.[21] Office staff have stolen prescription pads to create fraudulent paper prescriptions and called in fraudulent prescriptions. That they can do so with paper prescriptions is not a reason to facilitate their illegal activities with electronic prescriptions. DEA also notes that medical identity theft—where patient records are sold or misused—is a crime that often involves insiders. The *Report on the Use of Health IT to Enhance and Expand Health and Anti-Fraud Activities* cited a study that found that 70 percent of identity theft cases involved insider theft of data.[22]

This requirement will protect practitioners by eliminating the possibility that a staff member will be able to issue controlled substance prescriptions unless the practitioner grants them access to his authentication methods, which would make the practitioner legally responsible for any prescriptions that staff created. This requirement is also consistent with the HIPAA Security Guidance, issued on December 28, 2006, which recommended setting authorization levels particularly for portable devices and health record systems that can be remotely accessed.

DEA notes that role-based access control lists may need to be modified to comply with this requirement. Not every physician is a DEA registrant; not every DEA registrant is allowed to prescribe all Schedule II–V controlled substances. Authorizations for mid-level practitioners (e.g., nurse practitioners, physicians' assistants) vary across States. Service providers will need to ensure that their access control process reflects the actual authorizations of individuals and does not rely solely on roles.

To ensure that a prescription cannot be altered once it is ''signed,'' DEA is proposing that the prescription must be transmitted immediately on signing. Practitioners would be able to create a group of prescriptions and store them to be signed later. Agents of the practitioner (e.g., nurses) could also, at the practitioner's direction, enter some or all of the data into an electronic prescription as they can do for paper prescriptions. The practitioner, however, must authenticate to the system to sign the prescription because the practitioner is the ultimate authority for the prescription. If others prepare all or part of prescriptions, the practitioner could authenticate to the system and sign one or more prescriptions simultaneously depending on the system. If the system allows a practitioner to sign multiple prescriptions at once, DEA would require that the practitioner be required to indicate separately that he or she intends to sign each controlled substance prescription listed; this can be done by checking a box as some systems currently do. The critical requirement is that once the prescription is signed, it must be immediately transmitted so that there can be no question that someone else at the office had the opportunity to alter it. Many existing systems already have this feature. DEA notes that systems may apply varying labels to the signing function (e.g., sign, transmit); DEA does not think it is necessary to change these labels. The critical element is that the practitioners understand that when they use the function, they are exercising their authority to issue a controlled substance prescription and that they are responsible for accuracy, completeness, and validity of the prescription.

The other part of this requirement is that a controlled substance prescription must not be transmitted unless it has been ''signed.'' The system must be designed to prevent any transmission until the practitioner has ''signed'' the prescription. In addition, the system must not allow a prescription to be printed once it has been transmitted or to be transmitted if it was printed. These conditions are necessary to prevent a single prescription being used to generate multiple copies to be filled.

As noted above, the NCPDP SCRIPT standard does not currently include a field for a ''signature'' or for any indication that the prescription has been signed. DEA would require that controlled substance prescriptions include an indication that the prescription was signed; this indication could be a single character field. The industry has indicated that this alteration is feasible. It will provide pharmacies with additional assurance that the prescription was issued legally.

DEA welcomes comment on the current industry practices used to ''sign'' electronic prescriptions for noncontrolled substances and whether and how such practices prevent noncontrolled substance prescription forgery, fraud, and other related crimes.

Prescription data. Electronic prescriptions must contain the same information that DEA requires for paper prescriptions (21 CFR 1306.05): The date of issuance of the prescription;

[21] *http://www.nationalerx.com/pdf/NEPSI-eRx-faq.pdf.*

[22] The *Report on the Use of Health IT to Enhance and Expand Health Care Anti-Fraud Activities*, prepared for the Office of the National Coordinator, U.S. Department of Health and Human Services, September 30, 2005. *http://www.hhs.gov/healthit/hithca.html.*

practitioner's full name and address; practitioner's DEA registration number; patient's full name and address; drug name, strength, quantity, dosage form, and directions for use. DEA notes that for military or Public Health Service practitioners exempt from registration, the prescription must include the practitioner's service identification number or Social Security Number as required by 21 CFR 1306.05(h). This information may not be altered once the practitioner signs the prescription other than to reformat. The current version of NCPDP SCRIPT provides fields and codes for all of the required data elements, but not all of them are mandatory. For a controlled substance prescription, however, all of this information must be included. Other practitioner identifiers (State license number or National Provider Identifier) may not substitute for the DEA registration number. A system that completes practitioner and patient name and address only by linking to a National Provider Identifier (NPI) number and insurance records is not sufficient for DEA purposes for two reasons. First, practitioners will have a single NPI, but they may have multiple DEA registrations, particularly if they practice in more than one State. A prescription must have the correct DEA registration and location. Second, a system that assumes that details on the patient will be filled in by linking to insurance files will not account for the part of the population that does not have prescription drug insurance. As discussed above, multiple prescribers and their DEA registration numbers on a single prescription are also not acceptable. Electronic prescription systems would not be allowed to transmit a prescription for a controlled substance unless all of the required elements are complete.

DEA is also proposing to require that the system show the practitioner all of the DEA-required prescription information before the prescription is signed to ensure that a practitioner does not inadvertently misprescribe a controlled substance or sign a prescription created by an agent for his signature without having been presented with the contents. Although many systems do this, the RAND study indicated that some do not. In those cases, the practitioner sees only the drop down menus sequentially and may not have the opportunity to review the completed prescription. Where an agent enters the data for the prescription, it is particularly important that the practitioner be able to see the details to ensure that diversion is not occurring. DEA notes that the data may be presented in any format the system devises (e.g., arrayed like a paper prescription, a single line with the data selected shown); the essential items are the patient name and address, drug name, dosage form and units, quantity prescribed, directions for use, and the DEA registration number of the prescribing practitioner. DEA recognizes that systems may not routinely display the patient's address and seeks comments on whether displaying this information would pose technical problems.

DEA believes it is important to allow the signing and transmission of more than one prescription simultaneously. However, it is critical that the practitioner know, and positively indicate, which prescriptions are to be signed and transmitted. Where more than one prescription has been prepared at any one time, DEA is proposing to require that, prior to authenticating to the system, the practitioner indicate which prescription(s) are to be signed and transmitted. Such indication could be as simple as checking a box associated with each prescription the practitioner wishes to sign and transmit. DEA is not proposing any requirements to address a circumstance in which a prescription is not indicated for signature and transmission.

DEA would not allow alteration of any of the required information after the prescription is signed except to reformat. DEA does not believe that the intermediaries are altering the data because formulary checks appear to occur prior to signing. If, however, there are cases where the content of the required elements is altered (e.g., to change the prescribed drug to a generic drug) after signing, DEA would consider the prescription invalid and the parties that changed the data to have issued a prescription without being authorized to do so, a violation of the Controlled Substances Act.

Automatic timeout. For security reasons, many computer systems now lock the computer if it is not used for a period of time, often 5 or 10 minutes. The user must then reauthenticate himself to the system before being able to use the computer again. This feature ensures that there is a very limited possibility that someone else could use the computer or PDA after the practitioner authenticates to the system. This requirement is unlikely to be a problem for electronic prescription systems run by ASPs; if the feature does not exist in installed systems, it will require some reprogramming. DEA notes that automatic timeout after system inactivity is required under the CCHIT security criteria for EHRs, so should not impose a burden on those system providers. DEA is proposing that if the system is inactive for 2 minutes after the practitioner authenticates to the system to sign controlled substances prescriptions, the system must require the practitioner to reauthenticate himself to the system. DEA notes that it is not proposing that practitioners authenticate themselves to the system before creating the prescription, but only when the practitioner is ready to sign and transmit the prescriptions. Practitioners may create multiple prescriptions or have staff create the prescriptions for one or more patients, then authenticate to the system and sign the entire set at one time if the system allows this.

Digitally Signed Records. DEA is proposing that when an electronic prescription is signed and transmitted the first recipient would have to digitally sign and archive the digitally signed copy for five years from the date of issuance by the practitioner. Some electronic prescription systems already do this. In one case, the practitioner applies the service provider's digital signature when the practitioner signs the prescription; this is an acceptable practice under the proposed rule. Similarly, the first pharmacy system to receive the prescription (or the last intermediary transmitting it to the pharmacy) would have to digitally sign and archive a copy of the record as received. If the last intermediary digitally signs the record, it must forward both the record and the digitally signed copy to the pharmacy for dispensing. DEA notes that the service providers already have digital certificates.

As explained in detail below, digitally signing a record ensures that DEA and other law enforcement agencies can prove that the record is the prescription that the practitioner signed and the record that the pharmacy received. Industry representatives have stated that their internal audit trails provide similar evidence of record integrity; audit trails are computer functions that record each time a record is opened or altered. DEA has two concerns with relying on such audit trails for proof of record integrity. First, insiders will know how to turn off or erase audit trails. If they want to alter a prescription or insert fraudulent new prescriptions, they may be able to do so without leaving a trace. Second, DEA and other law enforcement agencies cannot be in the position of having to prove that such alterations did not occur each time they have to prove that a practitioner signed fraudulent prescriptions or a pharmacy altered a

record. The standard for criminal cases is ''beyond a reasonable doubt.'' If DEA relied on audit trails, it would have to subpoena both records and technical experts from each system and intermediary that handled each suspect prescription and hope that the possibility of insider action did not create a reasonable doubt. (As discussed in more detail below, insider threats to computer systems are relatively common.)

The burden of relying on intermediary and service provider audit trails would fall on the service providers and intermediaries as well. Even a simple case against a single practitioner could require substantial time for each service provider and intermediary as they would need to produce records and experts to explain the systems to grand juries, attorneys on both sides, and petit juries. Many diversion cases are not simple. For example, in February 2007, a county district attorney in New York filed charges against a Florida pharmacy and at least six practitioners in a case involving diversion of steroids (Schedule III). The investigation involved at least 20 branch offices of State, local, and Federal agencies in four States with connected investigations in two other States. If the prescriptions had been electronic, each service provider and intermediary could have been required to make records and experts available to each investigating agency. Neither the service providers, intermediaries, nor law enforcement would be well served by a system that demanded the industry prove the integrity of its systems every time a case is brought against a practitioner or pharmacy.

Digital Signatures. Digital signatures, as opposed to electronic signatures, are created as part of a public key infrastructure. A trusted party, a certification authority, conducts identity proofing and provides the subscriber with the means to generate an asymmetric pair of cryptographic keys. The subscriber retains control of the private key; the public key is available to anyone. What one of the keys encrypts only the other key can decrypt.

When a person digitally signs a record, the text of the record is run through an algorithm that produces a fixed-length digest (known as the hash). The private key is used to encrypt the digest. The encrypted digest is the digital signature. When the record is sent to someone else, both the plain text and the digital signature are sent along with the signer's digital certificate, which includes the public key. If the recipient wants to confirm that the record has not been altered during transmission, the recipient can use the public key to decrypt the digest. This step confirms who sent the message (i.e., no one other than the holder of the private key could have sent the message and the holder cannot repudiate the message). The recipient's system can run the plain text received through the same hashing algorithm. If the two digests match, the recipient knows that the message sent has not been altered.

The advantage of digital signatures is that they provide, in a single step, what other systems do not: a straightforward means of determining record integrity. If the first recipient of an electronic prescription signs it digitally, DEA will be able to prove what the practitioner signed. If the prescription is altered after that point, the practitioner will be able to demonstrate that he did not issue the altered prescription. Similarly, if the contents of the prescription sent and prescription received match, DEA and the intermediaries will be able to prove that the contents of the record were not altered in transit.

DEA is not proposing that practitioners digitally sign prescriptions or that pharmacies routinely validate prescriptions that are digitally signed because the existing system of intermediaries makes this requirement infeasible. As explained above, electronic prescriptions often need to be reformatted during transmission. This reformatting makes it impossible to validate the digitally signed record. That is, the digest generated for the prescription signed will not match the digest generated for the prescription received if even a single space is changed. DEA is, therefore, proposing only that the prescription as sent by the prescribing practitioner and as received by the dispensing pharmacy be digitally signed and archived. This approach will enable DEA and other law enforcement agencies to prove what the practitioner signed and what the pharmacy received. The approach also allows the service providers to apply their digital signatures, which most of them already have, rather than requiring the 1.2 million DEA-registered practitioners to obtain digital certificates. Digital signatures are an integral component of secure transmission systems in use by businesses that use the Internet.

The requirements for the digital signatures that the service providers or pharmacies apply are based on NIST FIPS standards for digital signatures and the hashing algorithm. Specifically, the signature would have to comply with FIPS 186–2, the digital signature standard. The algorithm used to process the record would have to comply with FIPS 180–2, the secure hash standard. Compliance with FIPS 186–2 requires compliance with FIPS 180–2. These standards are commonly used in the technology industry and, therefore, should not impose a burden on service providers; specifying the standards ensures the security of the digitally signed record.

Check on validity of the DEA registration. DEA is proposing that the validity of the DEA registration must be checked prior to dispensing a prescription. For paper prescriptions, this responsibility rests with the pharmacy. If a pharmacist has reason to doubt the validity of a prescription, he is required to, among other things, check the registration of the prescribing practitioner to determine whether, in fact, the practitioner is authorized to prescribe controlled substances in the schedule of the prescription. Chain pharmacies sometimes purchase the CSA registration database to conduct these checks. To parallel the paper system, DEA would require that prior to dispensing the pharmacy verifies that the practitioner is authorized by DEA to issue the prescription. DEA recognizes, however, that any of the service providers or intermediaries could offer this check as part of their service. Therefore, DEA is proposing simply that the registration be checked at some point prior to dispensing; if the check occurs before the prescription is delivered to the pharmacy, the record must indicate that the check has occurred and that the prescription is valid. If an electronic prescription service provider chooses to check the validity before transmitting the prescription and indicate that the check has occurred and the registration is valid, that would meet the requirement as would checks by any intermediary or pharmacy service provider. This requirement will give pharmacies greater assurance than they now have that the prescription is legitimate. DEA notes that regardless of which party checks the validity of the prescribing practitioner's DEA registration, the pharmacy is solely responsible and liable for the dispensing of the controlled substance. A pharmacy that relies on an intermediary or its own service provider to conduct the check must ensure that the reliance is warranted.

Pharmacy system record requirements. The pharmacy system must archive and retain the digitally signed prescription as received for five years from the date of receipt. The pharmacy system must require that each annotation include the information needed for paper prescription annotation (what was dispensed, by

whom, and when). The annotated record or linked records must be maintained for five years.

System security requirements. Beyond the requirements for handling controlled substance prescriptions at the point of origin, DEA is concerned about the security of the service providers' systems and whether that security protects against both insider and outsider threats. As noted above, insider threats may be a greater threat. Two FBI surveys on computer crime indicate that 42 to 44 percent of the companies surveyed reported insider misuse of their computer systems.[23] The 2006 survey also found that the most commonly used security technologies were directed toward outsiders. The Secret Service and Carnegie Mellon Institute have conducted studies of insider threats. They found that across all industries insiders who ''attacked'' company systems were likely to be disgruntled technology employees or former technology employees. In the financial sector, however, insiders did not hold technical positions. These insiders, who were usually acting for personal gain, attacked the system during work hours (70 percent) and in the work place (83 percent). In the financial sector, 78 percent of the cases involved modification or deletion of information.[24]

DEA is particularly concerned about insider threats. Although it is possible for hackers to break into computer systems, most service providers have invested in security technologies to protect against outsider attacks. It would also be possible for someone to create identity documents good enough to convince a service provider that the person was a DEA registrant, but this could be a costly exercise that could involve setting up a fictitious office. It is more likely that someone outside or inside a service provider organization will find an insider willing to create a fictitious subscriber, using a real practitioner's name and DEA registration number, who can then issue fraudulent prescriptions that the system, intermediaries and pharmacies will assume are genuine. Staff at intermediaries could also create and transmit fictitious prescriptions. The profits to be made from such action would be sufficient to bribe service provider insiders or to tempt them to take action on their own. In addition, with 10 percent of the adult population abusing prescription drugs at some time,[25] it is likely that some insiders or their family members or friends may be addicted to prescription drugs that they cannot obtain as easily elsewhere. DEA does not question the good intentions of service providers or intermediaries, but it would be naïve to think that they are immune from the threat of insider action when it is so widespread across all industries.

Pharmacy internal audits. For pharmacies, DEA is proposing that the pharmacy system include an internal audit trail; at the July 2006 public meeting regarding electronic prescriptions for controlled substances, the industry indicated that audit trails are a common feature of existing systems. The system operator would be required to define and implement a list of auditable events and conduct a daily analysis of the system to identify if any auditable events have occurred. The list of auditable events would have to include, at a minimum, attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in the controlled substances prescription system. The minimum list is based on the HIPAA definition of a security incident (45 CFR 164.304) and should, therefore, impose no new requirements on pharmacy systems, which are already subject to HIPAA. If the daily audit report identifies any events that indicate that the prescription system has been, or could have been, compromised, the pharmacy would be required to report this to DEA.

Pharmacy backup storage system. DEA is also proposing that the pharmacy system have a backup storage system for the prescription records required to be maintained by DEA. The backup system would have to be at another location so that it would not be subject to the same hazards (e.g., fires, power surges) as the main server. Such backup systems are common features provided by pharmacy system ASPs. DEA believes that pharmacies will generally need such systems for normal business reasons, particularly as their records become solely electronic. Backup systems will prevent the loss of records that DEA has seen when pharmacies have fires or power surges between the time DEA, or another law enforcement agency, serves a subpoena and the time the records must be delivered.

Third-party audits. DEA realizes that its registrants would not be able to determine, on their own, whether a particular service provider or system meets DEA's requirements. In addition, the security of the service provider's operations is critical to preventing insider threats and outsider attacks on the system. A registrant would have no way to determine whether a service provider had adequate protection against the range of potential security threats. It can be argued that service providers' primary goal is to sell their systems; the assertions that any service provider makes about its system cannot be accepted at face value. The accepted way for demonstrating that a system or a company is meeting a standard is to have a qualified third party audit the system or program and make a determination regarding the system's compliance. A qualified third party allows the party relying on the information the assurance that the determination is impartial and complete.

DEA considered developing a series of security requirements derived from NIST SP 800–53, which details security requirements for Federal information technology systems, and mandating that compliance with the requirements be verified through a third-party audit. DEA has concluded, however, that separate detailed standards were not warranted because an alternative approach would provide equivalent assurance of security practices at a lower cost. Detailed requirements based on NIST SP 800–53 could limit the flexibility of service providers to develop different procedures and practices that meet the need for security. Many service providers may already have adequate security practices and procedures in place, which might have to be altered to meet a NIST SP 800–53 requirement. DEA is aware that most private sector companies are unfamiliar with NIST SP 800–53. In addition, auditors would have to develop new protocols, a cost that would be passed on to the service providers. Because there are relatively few service providers, it is possible that there would not be an incentive for auditors to develop a common protocol that could be applied nationally. Another Federal agency that created third-party audit standards based on NIST SP 800–53 indicates that audits of compliance with a NIST SP 800–53-derived standard cost at least $250,000.

[23] 2005 FBI Computer Crime Survey and the 2006 CSI/FBI Computer Crime and Security Survey.

[24] Insider Threat Study: Illicit Cyber Activity in the Banking and Financial Sector, August 2004; Insider Threat Study: Computer System Sabotage in Critical Infrastructure Sectors, May 2005.

[25] Substance Abuse and Mental Health Services Administration. (2007). *Results from the 2006 National Survey on Drug Use and Health: National Findings detailed tables (Office of Applied Studies, NSDUH Series H–32, DHHS Publication No. SMA 07–4293. Rockville, MD. Table 1.18B—Nonmedical Use of Pain Relievers in Lifetime, Past Year, and Past Month by Detailed Age Category: Percentages, 2005 and 2006. http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6Results.cfm#TOC.*

DEA, therefore, is proposing that rather than attempting to dictate security requirements, the Administration would require electronic prescribing system service providers and pharmacies to obtain a third-party audit that addresses security and processing integrity. The third-party audit would also give practitioners and pharmacies a basis for determining if their systems meet DEA's standards. DEA seeks comments on this approach and whether this approach is preferable to a NIST SP 800–53-based audit approach.

Specifically, DEA is proposing that any system that will be used to create controlled substance prescriptions must have a third-party audit prior to accepting controlled substances prescriptions for processing and annually thereafter that meets the criteria for a SysTrust or WebTrust audit for security and processing integrity. For pharmacies, a SAS 70 audit would also be acceptable. As discussed below, SysTrust, WebTrust, and SAS 70 audits are professional services provided by qualified certified public accounting firms. For security, the audit determines whether the system is protected against unauthorized access (physical and logical); for processing integrity, the audit determines if the system processing is complete, accurate, timely, and authorized. SysTrust and WebTrust audits may also address issues of system availability, privacy, and confidentiality. Although practitioners and pharmacies may well be interested in these aspects of their systems, DEA does not believe that they are directly connected to the authentication and integrity of prescription records and, therefore, is not proposing to require audits that address these elements.

Third-party audits are frequently used by companies to prove compliance with standards and regulations. Organizations such as the International Standards Organization (ISO) routinely require third-party audits to demonstrate compliance and continuing compliance with its standards. Industry organizations, such as the American Chemistry Council, require third-party audits for their members to prove compliance with industry programs (e.g., Responsible Care in the chemical industry). The FDA recommends third-party audits for food processors and medical device manufacturers. The Federal Financial Institutions Examination Council (FFIEC), an interagency body that prescribes uniform principles, standards, and report forms for the Federal examination of financial institutions, allows third-party audits of technology service providers. Specifically, the Council cites American Institute of Certified Public Accountants (AICPA) Statement of Auditing Standards (SAS) 70 and Trust Services audits as providing the examination and information needed by Federally regulated financial institutions. FFIEC states that:

> SAS 70 provides a uniform reporting format for third-party reviews of technology service providers (TSP) to facilitate the description and disclosure of the service provider's processes and controls to customers and their auditors. SAS 70 is a widely recognized standard and indicates that a service provider has had its control objectives and activities examined by an independent accounting and auditing firm. A formal report including the auditor's opinion (service auditor's report) is issued to the TSP at the conclusion of the SAS 70 process. The report contains a detailed description of the TSP's controls and an independent assessment of whether the controls are in place and suitably designed for the service provider's operations. The independent assessment of controls is based on testing certain controls to determine whether they are designed and operating with sufficient effectiveness to achieve the related control objective for the specified time period.[26]

SAS 70 audits are intended for the company's internal use. AICPA has developed two Trust Services audits to provide information to external users. FFIEC describes them as follows:

> SysTrust—In this type of review, a licensed CPA provides independent verification that a TSP has effective controls in place so that the system can function reliably. The institution prepares a description of the aspects of the system subject to be reviewed so that the scope of the review is clear to readers of the report. This system description is attached to the CPA's report. The auditor determines the presence of system controls and tests the effectiveness of the controls during the period covered by the SysTrust report. If the review is an attest-level engagement, the CPA firm's attestation is represented by the report to management and may also be represented by a SysTrust seal on the institution's Web site.
>
> WebTrust—The objective of a WebTrust engagement is for a licensed CPA to provide independent verification that an institution's Web site complies with the Trust Services Principles and Criteria in the particular subject matter reviewed (i.e., confidentiality, security, etc.). If the engagement is an attest-level review, assurance is represented by the CPA's report to management. An institution whose Web site has met the Trust Services Principles and Criteria in a particular subject matter area is eligible to display the WebTrust seal for that area to provide independent verification that an institution's Web site is in compliance. Clicking on the WebTrust seal reveals the date the seal was granted and the date it expires, the site's business practices and policies, Trust Services Principles and Criteria used to examine the site, the report of the independent accountant, as well as links to other sites with active WebTrust seals.[27]

Some electronic prescription systems already obtain these audits and display the seals on their Web sites.

Because the AICPA Trust audits are already in use and widely recognized, DEA is proposing to specify their use. DEA, however, seeks comments on whether other recognized audit protocols exist that provide similar services to those covered by the SysTrust/WebTrust/SAS 70 systems. DEA recognizes that audits can be expensive; SysTrust audits can cost from $15,000 to $250,000 depending on the size of the company and complexity of the information technology system. These recognized audits, however, provide assurance to the service providers' customers and investors that the systems will protect them and their information.

For prescribing systems, DEA is proposing that service providers must make the audit report available to any practitioner currently using the service provider's system and any practitioner considering use of the system. DEA believes that, at a minimum, the service provider must make the report available on its Web site, although a service provider may choose to make the report available through other means as well. If the third-party audit determines that the system does not meet one or more of DEA's regulatory requirements regarding the electronic prescribing of controlled substances, or does not provide adequate security against insider and outsider threats, the service provider must not accept for transmission any controlled substance prescription. The service provider would be required to notify practitioners that they should not use the system to generate and transmit controlled substance prescriptions. The service provider must also notify DEA of the adverse audit report and provide the report to DEA. For service providers that install the prescription-writing system on a practitioner's computers and that are not involved in the subsequent transmission of the prescription, the service provider must notify its DEA registrant customers of the results of any third-party audit that finds that the system does not meet one or more of DEA's regulatory requirements regarding the electronic prescribing of controlled substances. The service provider must also notify DEA of the

[26] *http://www.ffiec.gov/ffiecinfobase/booklets/audit/audit_06_3_party.html.*

[27] *http://www.ffiec.gov/ffiecinfobase/booklets/audit/audit_06_3_party.html.*

adverse audit report and provide the report to DEA.

The practitioner must determine initially and at least annually thereafter that the third-party audit report of the service provider indicates that the system and service provider meet DEA's regulatory requirements regarding the electronic prescribing of controlled substances. If the third-party audit report indicates that the system or the service provider does not meet the requirements of this part, or the service provider notifies the practitioner that the system does not meet the requirements of this part, DEA is proposing to require that the practitioner must immediately cease issuance of electronic controlled substance prescriptions using the system. As DEA has discussed throughout this rule, electronic prescribing of controlled substances is in addition to existing methods for prescribing of these substances. Therefore, DEA believes that this requirement will not impede the prescribing of controlled substances by practitioners.

For pharmacy systems, DEA is proposing that service providers must make the audit report available to any pharmacy currently using the service provider's system. DEA believes that, at a minimum, the service provider must make the report available on its Web site, although a service provider may choose to make the report available through other means as well. If the third-party audit determines that the system does not meet one or more of DEA's regulatory requirements regarding the dispensing of electronic controlled substances prescriptions, or does not provide adequate security against insider and outsider threats, the service provider must not accept or process any controlled substance prescription. The service provider would be required to notify pharmacies that they should not use the system to accept and process controlled substance prescriptions. The service provider must also notify DEA of the adverse audit report and provide the report to DEA. For service providers that install the prescription-processing system on a pharmacy's computers and that are not involved in the subsequent processing of the prescription, the service provider must notify its DEA registrant customers of the results of any third-party audit that finds that the system does not meet one or more of DEA's regulatory requirements regarding the electronic prescribing of controlled substances. The service provider must also notify DEA of the adverse audit report and provide the report to DEA.

Prescribing logs. DEA is proposing that electronic prescription service providers generate and send practitioners a log of all controlled substance prescriptions the practitioner has written in the previous month. The practitioner would be required to review the log and indicate to the service provider that the practitioner has reviewed it. A record of the indication that the review has occurred must be retained for five years. Further, DEA is proposing that the service provider must make available, at the practitioner's request, a record of all controlled substance prescriptions transmitted by the practitioner over the previous five years, the length of time for which the service provider is required to retain the digitally signed archive of the controlled substance prescriptions. DEA is not proposing that the pharmacy system generate dispensing logs, as they are required to do for refills under 21 CFR 1306.22. The internal audit trail and daily check for auditable events will serve to identify problem records without the need for a daily printout of the daily dispensing record. DEA recognizes that audit trails are not perfect and that insiders can subvert them. Diversion from pharmacies, however, usually involves pharmacy staff altering records to cover diversion or knowingly filling fraudulent prescriptions. Most pharmacists and other pharmacy staff are unlikely to be knowledgeable enough to be able to manipulate audit system controls. DEA seeks comments regarding these record requirements.

Discussion of Other Proposed Rule Requirements

A. Practitioner Requirements

DEA emphasizes that the use of electronic prescriptions is voluntary. No registrant would be required by DEA to issue controlled substance prescriptions electronically. Those registrants that wish to do so, however, would have to comply with the rules governing electronic prescribing of controlled substances.

DEA would require that practitioners who are registered in more than one State have a separate key to sign prescriptions for their registration in each State. Some practitioners hold multiple registrations within a single State because they administer or dispense controlled substances directly to patients at multiple locations. As a practical matter, however, they may issue prescriptions in the State under a single registration (see 71 FR 69478, December 1, 2006 for further discussion of this). Consequently, DEA is proposing that practitioners would need to have multiple access keys only when they practice in more than one State. The ''keys'' could be stored on the same hard token. The practitioner would be responsible for selecting the correct DEA registration to use to sign the prescription.

The practitioner must ensure that only the practitioner uses the hard token and must not share the password with any other person. The practitioner must adopt procedures and controls to (1) secure the hard token and password against loss, theft, or unauthorized use, and (2) clearly identify any attempt to compromise the private key. In practice, a practitioner can secure the hard token by retaining physical control of it. The practitioner must not lend the token, whether it is a PDA, cell phone, smart card, or other device, to anyone. If the practitioner has reason to believe that the password or other method used to authenticate to the token has been compromised, the practitioner must notify the service provider as soon as possible, but no later than 12 hours after discovery, and change the authentication. The practitioner must report to the service provider the loss or theft of the hard token within 12 hours of identifying the loss or theft even if the practitioner does not believe that someone else will be able to authenticate to the system. If the hard token is lost or the key can no longer be accessed for any reason, the service provider must revoke the authorization to sign controlled substances prescriptions. If a practitioner fails to notify the service provider of the loss or compromise within 12 hours or if the practitioner purposefully allows someone else to use the hard token to create and sign electronic prescriptions, DEA will hold the practitioner responsible for any controlled substance prescriptions issued under his name.

Regarding the third-party audits of electronic prescribing service providers' prescribing systems, the practitioner must determine initially and at least annually thereafter that the third-party audit report of the service provider indicates that the system and service provider meet the DEA requirements for electronic prescribing systems. If the third-party audit report indicates that the system or the service provider does not meet DEA's requirements, or the service provider notifies the practitioner that the system does not meet DEA's requirements, the practitioner must immediately cease to issue electronic controlled substance prescriptions using the system.

B. Prescription Logs and Security Incidents

The practitioner would be required to review the log of his controlled substance prescriptions transmitted by the service provider and indicate that he has reviewed the log; the indication can be as simple as checking a box. DEA emphasizes that it does not expect practitioners to crosscheck the log with medical records. DEA expects practitioners to review the list to determine if something seems unusual, such as prescriptions for a patient the practitioner has not seen, prescriptions for substances the practitioner does not usually prescribe, or more prescriptions for a particular controlled substance than a particular patient would normally require. If the practitioner finds problems, the practitioner would be required to notify DEA and the service provider within 12 hours.

Pharmacy systems would also be required to conduct a daily analysis of the pharmacy system audit trail to check for auditable events. If an auditable event occurs, the pharmacy must determine whether it represents a security incident that compromised, or could have compromised, the integrity of the prescription system and report any such incidents to the system provider and DEA within one business day. Both the practitioner log check and the pharmacy audit trail analysis will assist registrants, service providers, and DEA in identifying any diversion that has occurred.

Finally, DEA is proposing that service providers must audit their records and systems at least once a day. Service providers would be required to notify DEA of any security incidents that could compromise the security of controlled substance prescriptions. These incidents would include, but not be limited to, the discovery that prescriptions were being written by nonregistrants (identity theft), that access had been granted without proper identity proofing, that prescriptions were being or could have been altered after transmission, or that outsiders had penetrated the system.

C. Electronic Records and Record Retention

Record retention. The CSA (21 U.S.C. 827(b)(3)) requires that records of dispensing, i.e., prescriptions retained by pharmacies, shall be kept and made available ''for at least two years'' for inspection and copying by authorized personnel, including DEA. As DEA has noted previously, however, many States require that these records be maintained for longer periods of time. DEA reviewed existing State board of pharmacy requirements regarding record retention and found that 21 States require that records be retained for two years, nine for three years, one for four years, 17 for five years, one for six years, and one State required that records be retained for seven years.

As has been mentioned throughout this document, electronic prescribing poses new threats and vulnerabilities for diversion due to the increased velocity of these authenticated automated transactions. Unlike the paper system, where only one prescription is created and provided to a patient who brings that prescription directly to the dispensing pharmacy, electronic systems provide the opportunity to create and transmit many prescriptions simultaneously. These many prescriptions can be simultaneously transmitted to pharmacies over a broad geographic area, without the need to physically move a paper prescription from one location to another. Further, as DEA has discussed, the introduction of service providers and other intermediaries into the system poses new vulnerabilities for insider attacks on the electronic prescribing systems.

DEA is concerned that a significant amount of time may elapse between the time a controlled substance is diverted and the time DEA becomes aware of the potential or suspected diversion. DEA is also concerned that administrative, civil, and criminal cases will become more complex and time-consuming as more parties become involved in the movement of the prescription from the practitioner to the pharmacy.

The statute of limitations for non-capital offenses is five years. That is, the United States cannot prosecute, try, or otherwise punish anyone for any non-capital offense unless the person is indicted, or an information instituted, within five years after the offense was committed (18 U.S.C. 3282). Due to the potential length and complexity of cases relating to the diversion of electronic prescriptions for controlled substances, DEA believes that a longer retention period is necessary and permissible within its statutory authority.

Therefore, to address these concerns, DEA is proposing to require that all records regarding electronic prescribing of controlled substances be maintained for five years from the date the record was created. This record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies. Records affected by this requirement would include, but are not necessarily limited to:

- The document received by the service provider from an entity permitted to conduct in-person identity proofing regarding the conduct of that in-person identity proofing for the specific practitioner.
- The electronic controlled substance prescription as digitally signed by the service provider or first processor.
- The electronic controlled substance prescription as digitally signed by the pharmacy or last intermediary.
- The dispensing annotations added to or linked to the prescription record.
- The backup copy of the pharmacy controlled substances prescription records.
- The internal audit trail records created by the pharmacy system.
- The monthly log of controlled substances prescriptions provided to each practitioner by the practitioner's service provider and the record of the indication by the practitioner that the log has been reviewed.
- The third-party SysTrust, WebTrust, or SAS 70 report of the electronic prescribing or pharmacy system.

DEA believes that these record retention requirements will not pose any new burdens on service providers and pharmacies. Many service providers indicate that they retain these records for longer periods of time, to comply with State laws and other Federal agency requirements. Further, as all of the records in question can be retained electronically, there will be limited costs associated with the storage of these records. DEA seeks comment regarding the extent to which service providers and intermediaries store electronic records of noncontrolled substance prescriptions.

Electronic Records. DEA is proposing that pharmacies must maintain records of electronic prescriptions and any linked records for five years. Records must be maintained electronically. Records regarding controlled substances that are maintained electronically must be immediately retrievable from all other records by prescriber's name, patient's name, drug dispensed, and date filled. They must be easily readable or easily rendered in a human readable format. The databases in which prescription records are maintained must be capable of exporting the records into database or spreadsheet format that will allow the data to be sorted by prescriber name, patient name, drug dispensed, and date filled. Such records must be made available to the Administration upon request. Records must also be capable of being immediately printed upon request.

D. Preventing This Rule From Being Exploited by Rogue Internet Operators

In recent years, there has been a significant rise in the amount of prescription controlled substances sold without a legitimate medical purpose by Internet-based entities such as so-called ''rogue Internet pharmacies.'' The typical ''rogue Internet pharmacy'' is actually a criminal conspiracy run by a Web ''entrepreneur'' who contracts with one or more unscrupulous DEA-registered practitioners to write prescriptions and one or more unscrupulous DEA-registered pharmacies to fill the prescriptions. Drug seekers easily find their way onto these Web sites through an Internet search engine (such as by typing the search terms ''hydrocodone no prescription'') or through spam e-mail advertisements. Once on such sites, the drug seeker is immediately shown a price list of controlled substances (with such prices usually inflated well above those of a legitimate pharmacy). After the drug seeker chooses the drug(s) he wants, the Web site assists the buyer in obtaining a prescription from an unscrupulous practitioner employed by the site, who has no bona fide doctor-patient relationship with the buyer. Generally, all that is needed for the buyer to obtain a prescription is to supply a credit card number, fill out a questionnaire and, in some cases, fax in some form of ''documentation'' that purports to show a medical condition.

The prescribing practitioner employed by the typical rogue Web site never sees the drug buyer in person, conducts no meaningful review of the documentation supplied by the buyer, and makes no attempt to rule out the possibility that the ''medical records'' supplied by the buyer are fraudulent. Instead, the practitioner employed by these sites generally writes as many prescriptions as possible, often from a location far from the patient. For example, DEA has found evidence that many practitioners located in the Caribbean have been employed by rogue Web sites to write prescriptions for ''patients'' located throughout the continental United States. Once the prescription has been generated, the same Web operation typically arranges for the prescription to be transmitted to the unscrupulous brick-and-mortar pharmacy, which fills it unquestioningly, turning a blind eye to the circumstances under which it was issued.

Using the foregoing methods, DEA estimates that the total amount of controlled substances illegally distributed via the Internet is well in excess of 100 million dosage units per year. DEA has taken numerous enforcement actions recently to shut down pharmacies, practitioners, and distributors found to have misused their DEA registrations to facilitate this Internet-based diversion. Yet, even with focused enforcement efforts, there will remain some unscrupulous individuals who will continue to seek to exploit the anonymity of the Internet to profit from the illegal sales of controlled substances. Moreover, given that a single rogue Web site can divert enormous amounts of controlled substances throughout the United States in a relatively short period of time, allowing such sites to operate even for brief periods can cause substantial harm to the public health and safety. It is, therefore, essential that DEA avoid any regulatory action that could be exploited by such rogue actors.

Based on the historical practices of these rogue Web sites and the claimed legal defenses they have put forth (asserting, for example, that their ''business model'' is having practitioners prescribe controlled substances without ever seeing the ''patient'' and without establishing a legitimate doctor-patient relationship), DEA is particularly concerned that the operators of these rogue sites might attempt to use this proposed rule as a justification for their illicit activities or to expand upon such activities. Absent a clear statement to the contrary in the regulations, operators of rogue sites might argue that, if their site generates prescriptions for controlled substances that are transmitted using electronic prescriptions in a manner that complies with authentication requirements of this proposed rule, they are automatically engaging in legal activity. Of course, all prescriptions for controlled substances must be issued for a legitimate medical purpose in the usual course of professional practice. Mere compliance with the authentication requirements of this proposed rule with respect to a given prescriptions does not—by itself—establish that the prescription was issued for a legitimate medical purpose. To avoid any possible confusion about this point, the proposed rule contains a provision that reaffirms this basic principle.

In addition, to minimize the likelihood that operators of rogue Internet sites would attempt to exploit this proposed rule, DEA wishes to reiterate some additional basic principles that the agency has stated in prior **Federal Register** documents. First, it is axiomatic that, in the absence of a bona fide doctor-patient relationship, a practitioner cannot satisfy the requirement of issuing a prescription for a legitimate medical purpose in the usual course of professional practice.[28] An arrangement whereby a Web site solicits drug seekers and refers them to practitioners who issue prescriptions for controlled substances without ever having seen the patient in person, based solely on such unreliable information as an online questionnaire, telephone conversation, or faxed documents that purport to be a drug buyer's medical records, inherently fails to satisfy the requirement of issuing a prescription for a legitimate medical purpose in the usual course of professional practice.[29] This is true regardless of whether the rogue Web site that operates in such a fashion utilizes paper, oral, faxed, or electronic prescriptions. Thus, it bears repeated emphasis that the use of electronic prescriptions in accordance with this proposed rule will in no way relieve the practitioner of the longstanding obligation to issue a prescription for a controlled substance only for a legitimate medical purpose in the usual course of professional practice. Likewise, as has always been the case, a corresponding responsibility will continue to rest with the pharmacist who fills the electronic prescription to ensure not only that the prescription was issued in accordance with the provisions for electronic prescribing contained in this proposed rule, but further that the prescription was issued for a legitimate medical purpose in the usual course of professional practice.

E. Other Prescription Issues

Transfers

A pharmacy would be allowed to transfer an original unfilled electronic prescription to another pharmacy if that pharmacy is unable to or chooses not to fill the prescription.

A pharmacy would also be allowed to transfer an electronic prescription with remaining refills to another pharmacy for filling provided the transfer is communicated between two licensed pharmacists. The pharmacy transferring the prescription would have to void the remaining refills in its records and note in its records to which pharmacy the prescription was transferred. The notations may occur electronically. The pharmacy receiving the transferred

[28] *See United Prescription Services, Inc.* (72 FR 50397, August 31, 2007); *Southwood Pharmaceuticals, Inc.* (72 FR 36487, July 3, 2007); *Trinity Health Care Corp., D/B/A/ Oviedo Discount Pharmacy* (72 FR 30849, June 4, 2007); *William Lockridge, M.D.*, (71 FR 77791, December 27, 2006); *Dispensing and Purchasing Controlled Substances over the Internet*, (66 FR 21181, April 27, 2001).

[29] *Id.*

prescription would have to note from whom the prescription was received and the number of remaining refills.

Applicability of Current Rules

The CSA provides that a pharmacist may only dispense a controlled substance in Schedule II pursuant to a written prescription, except in emergency circumstances, where a pharmacy may dispense pursuant to an oral prescription (21 U.S.C. 829(a)). The CSA further provides that a pharmacist may dispense a Schedule III and IV prescription pursuant to either a written or an oral prescription (21 U.S.C. 829(b)). The CSA was enacted in 1970, long before the advent of electronic prescriptions, and thus the Act makes no mention of electronic prescriptions. As a result, electronically created and transmitted prescriptions are subject to the same provisions of the CSA and DEA regulations that apply to paper prescriptions. The DEA regulations provide, as set forth in 21 CFR 1306.11 and 1306.21, that a pharmacist may dispense a controlled substance under a written prescription signed by the practitioner. This requirement applies equally to manually written and electronically written prescriptions. In either case, the prescription can be prepared by an agent of the practitioner, such as a nurse or office assistant, but only the practitioner can apply his signature to that prescription. Of course, for Schedule III through V controlled substances, the prescription could still be transmitted orally or by facsimile (including a manual signature by the practitioner) to the pharmacy at the practitioner's discretion.

IX. Summary of Proposed Rule Requirements

As has been discussed throughout this rulemaking, DEA is proposing electronic prescribing of controlled substances as an addition to, not a replacement of, existing prescribing and dispensing methods already permitted by the CSA and DEA regulations. DEA has discussed its law enforcement concerns as they relate to electronic prescribing and dispensing of controlled substances. Any requirements DEA implements for electronic prescribing and dispensing of controlled substances must ensure that DEA and other law enforcement needs under the Controlled Substances Act and implementing regulations can be met. DEA is convinced that its concerns can be addressed without creating insurmountable barriers to electronic prescribing. In addition, DEA wishes to adopt an approach that is flexible enough that future changes in technologies will not make the system obsolete or lock registrants into more expensive systems. As has been discussed throughout this rulemaking, many of the requirements DEA is proposing are already required by other Federal agencies or third-party organizations, and are in practice in electronic prescribing and electronic pharmacy systems today. The table below summarizes the requirements DEA is proposing by this rule, the rationale for each, and the current implementation status of each requirement.

TABLE 6.—SUMMARY OF PROPOSED REQUIREMENTS FOR ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

Requirement	Rationale	Current practice
In-person identity proofing § 1311.105	Ensures only DEA registrants are granted access and protects against identity theft.	Prescribing practitioners have ready access to hospitals, State licensing boards, and State/local law enforcement agencies, any of which may conduct in-person identity proofing.
Check validity of State license and DEA registration § 1311.105.	Ensures that only eligible practitioners are granted access.	At least some service providers already do this.
Maintain record of identity proofing § 1311.105	Provides a record that protects both the practitioner and service provider.	
Two-factor Level 4 authentication § 1311.110	Provides a direct link between the prescriber and prescription; prevents misuse of passwords without the practitioner's knowledge. Protects the practitioner from staff issuing prescriptions in the practitioner's name.	EHRs certified by CCHIT must support 2-factor authentication so majority of existing systems have this capability. HIPAA security guidance recommends 2-factor authentication.
Limit access to signing function § 1311.125	Ensures that only authorized registrants may sign controlled substance prescriptions.	EHRs certified by CCHIT must do this so majority of existing systems have this capability.
Automatic lockout after a period of inactivity § 1311.110.	Ensures that system cannot be accessed by other people once the practitioner has authenticated to the system.	EHRs certified by CCHIT must do this so majority of existing systems have this capability.
Prescription must contain all DEA data elements § 1311.115.	Meets the legal requirements for a controlled substance prescription.	All systems should already have this capability.
Present the required data elements to the practitioner § 1311.120.	Ensures that the practitioner has the opportunity to identify any miskeying.	Most systems present the full prescription information on a single screen.
Indicate that each prescription is ready to be signed § 1311.120.	Ensures that the practitioner has positively indicated that the prescription is to be transmitted when multiple prescriptions are being signed at one time.	Some existing systems already do this, requiring practitioners to check off each prescription they want to sign.
Authenticate to the system just before signing § 1311.125.	Ensures that only the practitioner signs the prescription.	Unclear when current systems require authentication. At least one requires entry of separate password to sign.
Transmit as soon as signed § 1311.130	Prevents any alteration after the practitioner has signed.	May be common practice in existing systems because signing is the equivalent of transmitting.
Do not transmit if printed; do not print if transmitted § 1311.130.	Prevents other staff from printing extra copies that can be used to divert.	May be a new function for most systems. (This requirement does not prevent printing a copy of a medical record.)
Indicate that the prescription was signed § 1311.125.	Provides assurance to pharmacy that the practitioner authorized the prescription.	A new field for electronic prescriptions; industry has indicated that this is not a problem.

TABLE 6.—SUMMARY OF PROPOSED REQUIREMENTS FOR ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES—Continued

Requirement	Rationale	Current practice
Generate monthly logs for practitioner review § 1311.140.	Provides practitioner a chance to review record and identify problems.	All systems should be able to generate records.
First recipient digitally signs the prescription as transmitted § 1311.130.	Provides record integrity. Ensures that DEA and the practitioner can prove what the practitioner signed.	At least one service provider is already doing so. Service providers all have digital certificates and the capability to sign records digitally.
Do not convert to fax if cannot be delivered § 1311.130.	Faxed prescriptions must be manually signed. Converting an electronic file to a fax during transmission creates an invalid written prescription.	May alter existing practice for some intermediaries. HHS has proposed removing an exemption from the SCRIPT standard for faxes.
No alteration of the content during transmission except for formatting § 1311.130.	Protects against changes during transmission	Industry says this does not happen so requirement should not impose a burden.
First pharmacy (or last transmitter) digitally signs the prescription as received § 1311.160.	Provides record integrity. Ensures that DEA and the pharmacy can prove what the pharmacy received. Eliminates the need to examine the intermediaries' records in most cases and provides a basis for identifying alteration at the pharmacy.	Intermediaries and at least some pharmacy system providers have digital certificates and the capability to sign records.
Check the validity of the prescriber's DEA registration (Pharmacy) § 1311.165.	Ensures that the practitioner is still authorized to issue prescriptions.	Many pharmacies already check the DEA database for registration information.
Store all of the DEA data in the pharmacy system § 1311.165.	Parallels paper records	Pharmacy systems already do this. Some may have problems with extensions to DEA numbers.
Have an internal audit trail and analyze for auditable events (Pharmacy) § 1311.170.	Provides a record of who annotated or altered a prescription. Needed to identify diversion at the pharmacy.	Most systems have this capability.
Electronic prescription records stored electronically. (pharmacy) § 1311.180.	All information is created and received electronically.	Pharmacy systems already maintain electronic information for paper prescriptions.
Have a backup system for records at another location. (Pharmacy) § 1311.170.	Protects against loss of records (accidental or intentional).	Many pharmacy system providers, particularly ASPs, have such backup systems.
SysTrust, WebTrust, or SAS 70 audit § 1311.150, § 1311.170.	Provides assurance of the physical and processing integrity of the system. Protects against insider and outsider attacks on the system.	At least one service provider already has adopted this audit.
Report security incidents § 1311.145, § 1311.155, § 1311.170.	Provides system provider and DEA with immediate notice of potential problems.	Imposes no system requirements.

X. Section-By-Section Discussion of the Proposed Rule

In Part 1300, DEA is proposing to add a new § 1300.03, definitions relating to electronic orders for controlled substances and electronic prescriptions for controlled substances. The definitions currently in § 1311.02 would be moved to § 1300.03. Definitions of the following would be added: Audit, audit trail, authentication, authentication protocol, electronic prescription, hard token, identity proofing, intermediary, paper prescription, PDA, service provider, token, and valid prescription. In addition, a definition of NIST special publication 800–63 and SAS 70, SysTrust, and WebTrust would be added. Where possible, DEA is proposing to use definitions taken from NIST publications (audit, audit trail, authentication, authentication protocol, hard token, identity proofing, service provider, and token). DEA is using standard definitions developed for information technology systems to reduce the possibility that service providers will be confused by definitions as they might be if DEA translated the definitions into ''plain'' language.

DEA is also proposing to add a definition of ''intermediary'' to cover any system that receives and transmits an electronic prescription after it is signed and before it is received by a pharmacy system. An intermediary could be the original service provider if it is the first recipient of the prescription, SureScripts or any other system that processes and reformats prescriptions, and a pharmacy system provider if it processes a prescription before routing it to the pharmacy.

Further, definitions of electronic and paper prescription would be added. The definition of electronic prescription would state that an electronic prescription must meet the requirements of parts 1306 and 1311. The definition also clarifies that a computer-generated prescription that is printed out or faxed is not an electronic prescription for DEA purposes. The definition of paper prescription clarifies that such prescriptions can be created on paper or computer-generated to be printed or faxed; all paper prescriptions must be manually signed. Finally, the definition of valid prescription from § 1300.02 would be repeated in the new section.

In Part 1304, § 1304.04 would be revised to limit records that cannot be maintained at a central location to paper order forms for Schedule I and II controlled substances and paper prescriptions. In paragraph (b)(1), DEA would remove the reference to prescriptions; all prescription requirements would be moved to paragraph (h). Paragraph (h), which details pharmacy recordkeeping, would be revised to limit the current requirements to paper prescriptions and to state that electronic prescriptions must be retrievable by prescriber's name, patient name, drug dispensed, and date filled. The electronic records must be in a format that will allow DEA or other law enforcement agencies to read the records and manipulate them; preferably the data would be downloadable to a spreadsheet or

database format that allows DEA to sort the data. The data extracted should only include the items DEA requires on a prescription. Records would also be required to be capable of being printed upon request.

In Part 1306, prescriptions, § 1306.05 would be amended to state that electronic prescriptions must be created and signed using a system that meets the requirements of part 1311 and to limit some requirements to paper prescriptions (e.g., the requirement that certain paper prescriptions have the practitioner's name stamped or hand-printed on the prescriptions). The section would also add ''computer printer'' to the list of methods for creating a paper prescription and clarify that a computer-generated prescription that is printed out or faxed must be manually signed. DEA is aware that in some cases, an intermediary transferring an electronic prescription to a pharmacy may convert a prescription to a facsimile if the intermediary cannot complete the transmission electronically. For controlled substance prescriptions, this is not an acceptable solution. The intermediary must notify the practitioner that the transmission could not be completed and have the practitioner create and sign a written prescription (for Schedule III, IV, or V controlled substances) before faxing it to the pharmacy. For most Schedule II prescriptions, the practitioner would have to provide a written prescription to the patient if notified that the transmission failed. The section would also be revised to divide paragraph (a) into shorter units.

Section 1306.08 would be added to state that practitioners may sign and transmit controlled substance prescriptions electronically if the systems used are in compliance with part 1311 and all other requirements of part 1306 are met. Pharmacies would be allowed to handle electronic prescriptions if the pharmacy system complies with part 1311 and the pharmacy meets all other applicable requirements of parts 1306 and 1311.

Sections 1306.11, 1306.13, and 1306.15 would be revised to clarify how the requirements for Schedule II prescriptions apply to electronic prescriptions.

Section 1306.21 would be revised to clarify how the requirements for Schedule III–V prescriptions apply to electronic prescriptions.

Section 1306.22 would be revised to clarify how the requirements for Schedule III–IV refills apply to electronic prescriptions and to clarify that requirements for electronic refill records for paper, fax, or oral prescriptions do not apply to electronic refill records for electronic prescriptions. Pharmacy systems used to process and retain electronic controlled substance prescriptions would have to comply with the requirements in part 1311. In addition, DEA is proposing to break up the text of the existing section into shorter paragraphs to make it easier to read.

Section 1306.25 would be revised to include separate requirements for transfers of electronic prescriptions. These revisions are needed because an electronic prescription could be transferred without a telephone call between pharmacists. Consequently, the transferring pharmacist must provide, with the electronic transfer, the information that the recipient transcribes when accepting an oral transfer.

Section 1306.28 would be added to state the basic recordkeeping requirements for pharmacies for all controlled substance prescriptions. These requirements are now in § 1304.22 and remain there as well. DEA is proposing to add them to part 1306 to place all of the requirements in a single part on prescriptions.

Part 1311 would be amended to add requirements related to electronic prescriptions for controlled substances.

Section 1311.02 providing definitions related to electronic orders for controlled substances would be revised to remove the definitions and replace them with a cross reference to new § 1300.03.

Section 1311.08 would be amended to add an incorporation by reference for NIST Special Publication 800–63.

A new subpart C would be added for the rules that govern the systems that may be used to issue and process electronic controlled substance prescriptions and the responsibilities of practitioners and pharmacies.

In § 1311.100, DEA would state that only DEA registrants or persons exempted from registration under part 1301 would be allowed to issue electronic prescriptions for controlled substances and only if they use a system and service provider that meet the requirements of part 1311. An electronic prescription for controlled substances issued through a system and service provider that did not meet the requirements of part 1311 would not be considered valid. The section would reiterate the requirement from § 1306.05 that the practitioner is responsible if the prescription does not conform in all essential respects to the CSA and implementing regulations.

Sections 1311.105 through 1311.150 would establish minimum requirements that a service provider and system must meet before a practitioner would be able to use the system to create and sign an electronic controlled substance prescription. Although the service providers and their systems must meet the requirements, the ultimate responsibility rests on the practitioner to use only a system and service provider that comply with DEA's requirements.

Section 1311.105 would require that the service provider receive a document regarding in-person identity proofing of the prescribing practitioner by an entity authorized by DEA to conduct the identity proofing. The service provider must check the DEA registration and State licensure to ensure they are current and in good standing, and maintain records of the identity proofing.

Section 1311.110 would require the system to use two-factor authentication that meets the requirements of NIST SP 800–63, level 4 as discussed above. The practitioner must reauthenticate to the system if the system is inactive for more than 2 minutes. The system must provide separate authentication protocols for separate DEA registrations that a practitioner uses to issue controlled substances prescriptions. Finally, the authentication protocol must expire no later than the expiration date of the DEA registration with which it is associated. A DEA registration is valid for three years and can be renewed prior to its expiration.

Section 1311.115 would require that electronic prescriptions for controlled substances contain all of the information required under paragraph (b) of that section and § 1306.05. It would also require that a controlled substance prescription include only the DEA number and practitioner information for the prescribing practitioner. As discussed above, the SCRIPT standard allows multiple DEA numbers to be associated with a prescription; this is not acceptable to DEA.

Section 1311.120 would set the requirements for creating an electronic prescription as discussed above. Consistent with current regulations governing paper prescriptions, DEA is proposing that the electronic prescribing system may allow the registrant or his agent to enter data for a controlled substance prescription, but only the registrant may sign and authorize the prescription. This would include the requirement that, where more than one controlled substance prescription has been prepared, the practitioner positively indicate that he has reviewed and approved the information for each

prescription prior to signing and authorizing electronic transmission of the prescriptions.

Section 1311.125 would set the requirements for signing an electronic prescription as discussed above. This would include the practitioner's declaration that information contained in the record constitutes the practitioner's legal authorization and signature.

Section 1311.130 would require that the system transmit the prescription immediately upon signing. The section would disallow the printing of an electronically transmitted prescription and would also disallow the electronic transmission of a printed prescription as discussed above. These requirements are to prevent an individual electronic prescription from being transmitted more than once to a pharmacy (or pharmacies). The service provider or first recipient would be required to digitally sign and archive a copy of the prescription as received. Finally, the section would specify that the DEA required contents of the prescription could not be altered after signature without rendering the prescription invalid. The contents could be reformatted; reformatting includes altering the structure of fields or machine language so that the receiving pharmacy system can read the prescription and import the data into the system.

Section 1311.135 would set the requirements revoking the authentication protocol used to sign controlled substances prescriptions upon notification that the password or token has been compromised, lost, or stolen or when the DEA registration expires unless the registration has been renewed and at any time that the registration is suspended or revoked.

Section 1311.140 would require the service provider to generate and transmit to the practitioner a log of all controlled substance prescriptions written under the practitioner's DEA number in the previous month. The section would also require that the service provider make available, at the practitioner's request, a record of all controlled substance prescriptions transmitted over the previous five years.

Section 1311.145 would require the service provider to notify DEA of certain security incidents, as discussed above.

Section 1311.150 would require each service provider to have at least an annual third-party SysTrust or WebTrust audit for security and processing integrity as well as compliance with part 1311. Audits must be conducted prior to accepting any controlled substances prescriptions for transmission and annually thereafter. The audit report must be made available to any practitioner using or considering use of the system. If the audit finds that the system does not meet the requirements of the part, the service provider must not transmit controlled substance prescriptions and must notify practitioners that they should not attempt to send electronic controlled substance prescriptions until the problems have been addressed and another audit indicates that the system meets the requirements of part 1311.

Section 1311.155 would specify the practitioner's responsibilities as discussed above. The section would require practitioners to check the third-party audit reports and notifications from the service providers about system inadequacies and cease to use the system for controlled substance prescriptions if the audit report or service provider indicated problems. The practitioner would be required to provide, or cause to be provided, documents regarding in-person identity proofing to the service provider. The practitioner would be required to maintain sole possession of the hard token and notify the service provider no later than 12 hours after the discovery of its loss or theft or any indication that the hard token had been compromised. The practitioner would be required to check the monthly log and indicate having done so. The section would reiterate that the practitioner has the same responsibility for the validity of an electronic prescription as the practitioner does for a paper prescription.

Section 1311.160 would require the pharmacy or the last system transmitting the prescription to the pharmacy to digitally sign and archive the prescription record.

Section 1311.165 would require the pharmacy to check the validity of the DEA registration prior to dispensing the prescription. The pharmacy system must reject a controlled substance prescription if it is not signed or is otherwise not valid. The pharmacy system would have to be able to include all of the information required under part 1306 in the electronic record and be capable of downloading the records in a readable and sortable format, as well as printing the records, if requested.

Section 1311.170 would specify the security requirements for the pharmacy system including a backup storage system at another location, maintaining an internal audit trail, the implementation of a list of auditable events, a daily internal audit to identify if any auditable events have occurred, reporting any security incidents that could affect the integrity of the prescription records, and the annual SAS 70 or SysTrust audit. Audits must be conducted prior to accepting any controlled substances prescriptions for processing and annually thereafter. The audit report must be made available to any pharmacy using or considering use of the system. If the audit finds that the system does not meet the requirements of the part, the service provider must not process controlled substance prescriptions and must notify pharmacies that they should not attempt to process electronic controlled substance prescriptions until the problems have been addressed and another audit indicates that the system meets the requirements of part 1311.

Section 1311.175 would specify the pharmacy's responsibility not to dispense controlled substances in response to an electronic prescription if the pharmacy's system does not meet the requirements of part 1311. In addition, the pharmacy must not dispense a controlled substance if the DEA registration of the prescriber was not valid at the time of signing. Finally, the section would state that nothing in part 1311 relieves a pharmacy of its corresponding responsibility to dispense only in response to a prescription written for a legitimate medical purpose by a prescribing practitioner acting in the usual course of professional practice.

Section 1311.180 would specify recordkeeping requirements for records required by part 1311.

XI. Digitally Signed Prescriptions for Federal Health Care Agencies

Federal healthcare providers have indicated that the electronic prescription option described above is not consistent with the electronic prescription system they currently use, a system that is based on public key infrastructure and digital signature technology. They also stated that the proposed rule described above did not meet their security needs. Thus, these Federal health care providers indicated that their existing system based on public key infrastructure and digital signature technology is more secure than, and incompatible with, the above system requirements that DEA is proposing. As a result, if they were obligated to adhere to the above system requirements, they would have to abandon their existing systems in favor of a less secure system, and would have to incur substantial cost and devote significant time to do so. Such a result would plainly be counterproductive. For these reasons, DEA is proposing—for Federal health care systems only—a

second approach that is consistent with their current systems. Federal health care systems will also have the option of using the above system that will be allowable for all practitioners in the private sector. The two systems have some elements in common—for example, the pharmacy requirements are almost identical—but the digital signature option adds some steps and removes others as compared with the electronic prescription system.

Public Key Infrastructure and Digital Signatures. Digital signatures are created as part of a public key infrastructure (PKI). In a PKI system, a certification authority (CA) verifies the identity of an applicant and issues a digital certificate to the applicant. A Certification Authority operates under a publicly available Certificate Policy, a set of rules that covers subjects such as obligations of the Certification Authority, obligations of certificate holders, enrollment and renewal procedures, operational requirements, security procedures, and administration.[30] A digital certificate is a data record that contains, at a minimum, the identity of the issuing Certification Authority, identity information for the certificate holder, the public key that corresponds to the certificate holder's private key, validity dates, and a serial number. The certificate is digitally signed by the CA. The certification authority provides the subscriber with the means to generate an asymmetric pair of cryptographic keys. The subscriber retains control of the private key; the public key is available to anyone. What one of the keys encrypts, only the other key can decrypt.

When a person digitally signs a record, the text of the record is run through an algorithm that produces a fixed-length digest (known as the hash). The private key is used to encrypt the digest. The encrypted digest is the digital signature. When the record is archived or sent to someone else, both the plain text and the digital signature are sent along with the signer's digital certificate, which includes the public key. If the recipient wants to confirm that the record has not been altered during transmission, the recipient can use the public key to decrypt the digest. This step confirms who sent the message (i.e., no one other than the holder of the private key could have sent the message and the holder cannot repudiate the message). The recipient's system can run the plain text received through the same hashing algorithm. If the two digests match, the recipient knows that the message sent has not been altered. For an in-depth explanation of digital signatures, see NIST FIPS 186–2.

Discussion of Proposed Requirements for Digitally Signed Prescriptions

Certification Authorities and Digital Certificates. Because this alternative applies only to Federal agencies, DEA is proposing that the Certification Authority will be one that is operated under the Federal PKI Bridge Certificate Policy and is either a Federal Certification Authority or cross-certified with a Federal CA. Digital certificates are already an option for Federal employees as part of the Personal Identification Verification (PIV) cards (usually a smart card). DEA, therefore, is proposing that a PIV or other Federal identity card to be used for signing controlled substance prescriptions include a digital certificate. Federal identity proofing and the smart card with a digital certificate already meet Assurance Level 4, so no further requirements are needed. PIV cards include both the holder's photograph and a biometric.

As with the proposed electronically signed prescription system, the system provider (the Federal agency) would be required to set access controls, set lock-out times at 2 minutes, require the practitioner to indicate which prescriptions he is authorizing when signing multiple controlled substance prescriptions at one time, provide screens showing the prescription information, and show the warning screen prior to signing. The system would be required to have the practitioner authenticate to the system just prior to signing. The system provider would also be required to check the CA's certificate revocation list (CRL) prior to transmission to ensure that the certificate is still valid. The CRL may be cached until a new CRL is issued.

DEA is proposing that any software system may be used to sign electronic controlled substances prescriptions provided that it has been enabled to process digital signatures and that the PKI module meets the following requirements:

1. The encryption module must comply with FIPS 140–2.
2. The digital signature generation system must comply with FIPS 186–2.
3. The secure hash algorithm must comply with FIPS 180–1.
4. For software implementations, when the signing module is deactivated, the system must clear the plain text password from the system memory to prevent the unauthorized access to, or use of, the private key.
5. The system must have a time system that is within five minutes of the official National Institute of Standards and Technology (NIST) time source.

Item four would ensure that the password cannot be retrieved from the certificate holder's computer memory following its use. Software systems may not automatically clear items from memory when the application is shut down. Therefore, it is necessary to specify that the system clear the password from the system's memory whenever the signing application is closed to ensure that someone cannot recover the password. Item five requires the system to have a time system within five minutes of the official National Institute of Standards and Technology time source. It is important that all users of digitally signed electronic prescriptions be synchronized to a single, consistent time source.

Once the prescription record is digitally signed, both the record and the digital signature must be archived. DEA is proposing that the system provider would be able to adopt one of two options for transmission after signing. The system provider could require transmission immediately on digitally signing or the system provider could ''lock'' and archive the prescription as digitally signed and allow other elements (e.g., pharmacy URL) to be added later. The ''lock'' would have to ensure that any element that was digitally signed could not be altered prior to transmission. For example, the system provider could program its system so that only the DEA-required elements would be digitally signed and only those elements and their digitally signed version are archived.

Unlike the electronically signed prescription approach, the system provider would not be required to apply its own digital signature to the record received from the prescribing practitioner. Because digital certificates from a Federal CA and digital signatures provide a level of security and record integrity that electronically signed prescriptions do not have, DEA is not proposing that a monthly log be generated and checked for digitally signed prescriptions.

When prescriptions are transmitted to retail pharmacies, they are frequently reformatted, making it impossible to validate a digitally signed prescription. DEA is not, therefore, proposing that the digital signature be transmitted with the

[30] National Institute of Standards and Technology. Special Publication 800–32 *Introduction to Public Key Technology and the Federal PKI Infrastructure; February 26, 2001. http://csrc.nist.gov/publications/nistpubs/800-32/sp800-32.pdf.*

prescription. This provision should eliminate the concern that intermediaries had about the difficulty of transmitting the digital signature. The pharmacy would be required to digitally sign the record as received and archive it, as with electronically signed prescriptions. Where a prescription is sent to a Federal pharmacy, however, the Federal agency may elect to transmit the digital signature and have the pharmacy validate the prescription. In that case, the Federal pharmacy would not be required to digitally sign the prescription. The other pharmacy requirements would be the same as for electronically signed prescriptions. The pharmacy would be required to check the DEA registration and maintain internal audit trails with daily computer checks for auditable events.

DEA is also proposing that Federal agencies using digital signatures would have to have an annual third-party audit of their system processing integrity to ensure that the systems meet DEA's requirements. Prescribing practitioners' use of digital certificates from a Federal or cross-certified CA would make insider identity theft much more difficult, eliminating the need to require the audit to review system security as is the case for the electronically signed prescription systems.

The practitioner would be required to notify the CA if the hard token was lost, stolen, or compromised within 12 hours of discovery of the loss, theft, or compromise. The CA would be required to revoke the certificate upon notification. These requirements are already met by the Federal systems.

Section-By-Section Discussion of the Proposed Rule for Digitally Signed Controlled Substances Prescriptions for Federal Health Care Agencies

In Part 1311, as proposed to be amended as discussed above, DEA is proposing to add a new Subpart D regarding requirements for electronic prescriptions for controlled substances for Federal health care agencies.

Section 1311.200 would state that a practitioner prescribing controlled substances at a Federal health care facility in the course of their official duties may issue a controlled substance prescription electronically if the practitioner is registered as an individual practitioner, or exempt from the requirement of registration, and is authorized under the registration or exemption to dispense the controlled substance, and the practitioner uses an electronic prescription system that meets all of the applicable requirements of the subpart. DEA would propose to define ''Federal health care facility'' as a hospital or other institution that is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Department of Veterans Affairs, Public Health Service, or Bureau of Prisons). An electronic prescription for controlled substances issued through a system that did not meet the requirements of part 1311 would not be considered valid. The section would reiterate the requirement from § 1306.05 that the practitioner is responsible if the prescription does not conform in all essential respects to the CSA and implementing regulations.

Section 1311.205 would establish requirements for issuance and storage of digital certificates. It would require that only Federal Certification Authorities or Certification Authorities cross-certified with a Certification Authority operated by the Federal Public Key Infrastructure Policy Authority may issue digital certificates to practitioners prescribing controlled substances at a Federal health care facility in the course of their official duties to sign electronic controlled substance prescriptions. The digital certificate must be stored on a hardware token that meets the requirements of NIST SP 800–63 Level 4.

Section 1311.210 would state the system requirements for digitally signed prescriptions. Any system may be used to digitally sign electronic prescriptions for controlled substances provided that the system has been enabled to accept digitally signed documents and that it meets the requirements discussed above. DEA would require the system to use two-factor authentication that meets the requirements of NIST SP 800–63, Level 4 as discussed above. The practitioner must reauthenticate to the system if the system is inactive for more than 2 minutes.

Section 1311.215 would require that a digitally signed electronic prescription for a controlled substance created by the system must include all of the data elements required under part 1306.

Section 1311.220 would set the requirements for creating an electronic prescription. Consistent with current regulations governing paper prescriptions, DEA is proposing that the electronic prescribing system may allow the registrant or his agent to enter data for a controlled substance prescription, but only the registrant may sign and authorize the prescription. The system must display information regarding the prescriptions including: The patient's name and address; the name of the drug being prescribed; the dosage strength and form, quantity, and directions for use; and the DEA registration number under which the prescription will be authorized. Finally, the section would require that, where more than one controlled substance prescription has been prepared, the practitioner positively indicate that he has reviewed and approved the information for each prescription prior to signing and authorizing electronic transmission of the prescriptions.

Section 1311.225 would set the requirements for signing an electronic prescription. The practitioner must authenticate to the system using two-factor authentication. This would include the practitioner's declaration that information contained in the record constitutes the practitioner's legal authorization and signature. DEA would require the system to check the certificate revocation list of the Certification Authority that issued the digital certificate of the practitioner who digitally signed the controlled substance prescription. If the certificate is not valid, the system would not be permitted to transmit the prescription. DEA would permit the certificate revocation list to be cached until the Certification Authority issues a new certificate revocation list. If the prescription is being transmitted to a pharmacy that does not accept digitally signed prescriptions, DEA would require the system to include in the data file transmitted an indication that the prescription was signed by the issuing practitioner.

Section 1311.230 would disallow the printing of an electronically transmitted prescription and would also disallow the electronic transmission of a printed prescription as discussed above. These requirements are to prevent an individual electronic prescription from being transmitted more than once to a pharmacy (or pharmacies). The system would be required to retain the archived digitally signed prescription for five years from the date of issuance by the practitioner. Finally, the section would specify that the DEA required contents of the prescription could not be altered after signature without rendering the prescription invalid. The contents could be reformatted; reformatting includes altering the structure of fields or machine language so that the receiving pharmacy system can read the prescription and import the data into the system.

Section 1311.235 would set the requirements for revocation of access authorization. The system would be required to revoke access to sign controlled substance prescriptions on the expiration date of the practitioner's DEA registration, if applicable, unless the Federal agency determines that the

registration or Federal agency authorization has been renewed. The system would be required to check the DEA CSA database at least once a week and revoke access to signing controlled substance prescriptions for any practitioner using the system whose registration or Federal agency authorization has been terminated, revoked, or suspended.

Section 1311.245 would require the Federal agency to notify DEA of certain security incidents, including:

- An individual who is not a DEA registrant authorized by the Federal agency to prescribe controlled substances in the course of their official duties at the Federal agency has been granted access to issue controlled substance prescriptions.
- Access to issue controlled substance prescriptions has been granted to a person using another person's identity.
- Prescription records have been created or altered by an employee not authorized to create or annotate a controlled substance record.
- There have been one or more successful attempts to penetrate the system from the outside.
- The Federal agency has identified any other incident that may indicate that the integrity of the system in regard to controlled substance prescriptions has been compromised.

Section 1311.250 would require the Federal agency to have a third-party audit to verify that the system used to create and transmit controlled substance prescriptions meets the requirements of this subpart prior to accepting any controlled substances prescriptions for transmission and annually thereafter. If the third-party audit finds that the system does not meet one or more of the requirements of the part, the system must not accept for transmission any controlled substance prescription. The Federal agency must also notify the Administration of the adverse audit report and provide the report to the Administration.

Section 1311.255 would specify the practitioner's responsibilities as discussed above. The practitioner would be required to maintain sole possession of the hard token and notify the Certification Authority no later than 12 hours after the discovery of its loss or theft or any indication that the hard token had been compromised. The section would reiterate that the practitioner has the same responsibility for the validity of an electronic prescription as the practitioner does for a paper prescription.

Section 1311.260 would require that if a pharmacy receives a controlled substance prescription from a Federal agency system that is not transmitted with its digital signature, either the pharmacy must digitally sign the prescription immediately upon receipt, or the last intermediary transmitting the record to the pharmacy must digitally sign the prescription immediately prior to transmission and transmit to the pharmacy the prescription and the digitally signed record. The pharmacy must archive the record as received and the digitally signed copy. If a Federal pharmacy receives a digitally signed prescription that includes the digital signature, the pharmacy must validate the prescription and archive the digitally signed record. The pharmacy record must retain an indication that the prescription was validated upon receipt. No additional digital signature is required.

Section 1311.265 would require the pharmacy to check the validity of the DEA registration prior to dispensing the prescription. The pharmacy system must reject a controlled substance prescription if it is not signed or is otherwise not valid. The pharmacy system would have to be able to include all of the information required under part 1306 in the electronic record and be capable of downloading the records in a readable and sortable format, as well as printing the records, if requested.

Section 1311.270 would specify the security requirements for the pharmacy system including a backup storage system at another location, maintaining an internal audit trail, the implementation of a list of auditable events, a daily internal audit to identify if any auditable events have occurred, reporting any security incidents that could affect the integrity of the prescription records, and the annual third-party audit to ensure compliance with the requirements of this part. Audits must be conducted prior to accepting any controlled substances prescriptions for processing and annually thereafter. If the audit finds that the system does not meet the requirements of the part, the system must not process controlled substance prescriptions until the problems have been addressed and another audit indicates that the system meets the requirements of part 1311. The Federal agency must also notify the Administration of the adverse audit report and provide the report to the Administration.

Section 1311.275 would specify the pharmacy's responsibility not to dispense controlled substances in response to an electronic prescription if the pharmacy's system does not meet the requirements of part 1311. In addition, the pharmacy must not dispense a controlled substance if the DEA registration of the prescriber was not valid at the time of signing. Finally, the section would state that nothing in part 1311 relieves a pharmacy of its corresponding responsibility to dispense only in response to a prescription written for a legitimate medical purpose by a prescribing practitioner acting in the usual course of professional practice.

Section 1311.280 would specify recordkeeping requirements for records required by Subpart D of part 1311.

XII. Incorporation by Reference

The following standard is proposed to be incorporated by reference:

NIST SP 800–63, Electronic Authentication Guideline, April 2006.

XIII. Required Analyses

Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), DEA must determine whether a regulatory action is ''significant'' and, therefore, subject to Office of Management and Budget review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal government or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A copy of the *Initial Economic Impact Analysis of the Electronic Prescriptions for Controlled Substances Rule* can be obtained by contacting the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7297. The initial analysis is also available on DEA's Diversion Control Program Web site at *http://www.deadiversion.usdoj.gov*. DEA seeks comments on the assumptions used in the economic analysis and is interested in any data that commenters can provide on the time required to comply with the proposed rule.

It has been determined that this Notice of Proposed Rulemaking is an economically significant regulatory action; therefore, DEA has conducted an analysis of the options. The following sections summarize the economic analysis conducted in support of this proposed rule.

Options Considered

DEA considered four options for the electronic prescribing of controlled substances: the rule as proposed with service providers conducting the identity proofing (Base Case); the rule as proposed (Option 1); a modified PKI option (not limited to Federal agencies) (Option 2); and an option that allowed the use of any existing electronic system with no additional requirements except callbacks from the pharmacy to the practitioner to verify the authenticity and integrity for all controlled substance prescriptions (Option 3). Table 7 shows the differing requirements for the rule elements for each of the options.

TABLE 7.—OPTIONS CONSIDERED

Requirement	Base case	Option 1	Option 2	Option 3
Identity Proofing	Conducted by service provider.	Conducted by hospital, state board, law enforcement.	Conducted by hospital, state board, law enforcement.	N/A.
Two-factor, Hard token	Required	Required	Required	N/A.
Authentication protocol	Issued by service provider	Issued by service provider	Digital certificate from CA	N/A.
System requirements	Required	Required	Required	N/A.
Digitally signed record	System level	System level	Practitioner	N/A.
Pharmacy	Digitally sign record on receipt.	Digitally sign record on receipt.	Validate practitioner digital signature.	Call practitioner to confirm each prescription.
Internal Audits	Required	Required	Required	N/A.
Third-party audits	SysTrust/SAS 70 security and processing.	SysTrust/SAS 70 security and processing.	Processing integrity	N/A.

Universe of Affected Entities

The entities that are most directly affected economically by the adoption of electronic prescriptions for controlled substances fall into two groups—practitioners who sign prescriptions and the firms that provide the computer and Internet software and services required for the creation, transmission, and receipt of electronic prescriptions. These firms serve either practitioners' offices or pharmacies. The affected universe does not include pharmacies directly, because the rule does not require any change in their operating practices; although their computer systems may need to be updated, the additional prescription processing steps (primarily digitally signing the record on receipt) will be handled by the system, not the pharmacist. For options 1 and 2, DEA-registered hospitals or other officials allowed to conduct identity proofing would also be affected.

The registered practitioners are primarily physicians, dentists, and mid-level practitioners (physician's assistants and nurse practitioners). Most other practitioner registrants are less likely to prescribe as opposed to administer or dispense controlled substances (e.g., veterinarians).

As discussed above, the service providers are vendors of the computer software and Internet services required by practitioners' offices for electronic creation and transmission of prescriptions and of the services required by pharmacies for receiving and processing electronic prescriptions. Many service providers to practitioners are application service providers (ASPs). Some of the service providers to pharmacies are ASPs, but most are not. Table 8 displays data on current numbers of practitioners and estimated future growth rates.

TABLE 8.—PRACTITIONER UNIVERSE

Affected Universe—Practitioners		
	Current No.	Future annual growth rate (percent)
Physicians	312,759	0.1
Dentists	170,969	0.5
Mid-levels	89,744	2.2
Total	573,472	0.5

The number of physicians is based on CDC data on the number of physicians in office-based practices. Current numbers for dentists and mid-level practitioners are DEA registrants as of December 3, 2007, with two modifications. The number of mid-level practitioners reported in this count includes, in addition to physician's assistants and nurse practitioners, workers in other health occupations who rarely sign prescriptions and who, therefore, have not been included. In addition, because many mid-level practitioners work at hospitals, the total was reduced by 25 percent because these practitioners may not write prescriptions. Estimated growth rates are based on recent trends. Regarding physicians, the trend since 2000 indicates a very slight negative growth rate. DEA does not believe this downward trend will continue; therefore, an annual growth rate for physicians of 0.1 percent has been estimated. The rate for the total number is the weighted average of the separate rates.

While the current count of systems certified by SureScripts or CCHIT (or both) for practitioners is 119, DEA has adjusted that figure downward to 110 for Year 1 of the analysis. With 119 firms offering these services and products to practitioners, it seems certain that some of them are in a marginal business condition with respect to this market. Consequently, DEA projects a steady diminution over time in the number of firms. It also seems reasonable to assume that some of them will withdraw from the market at the outset. There are three reasons for this result. First, the market has already seen firms leave the market as the demand for the products has not met expectations. Second, the security arrangements at some firms may be insufficient to withstand the required security audit, and, for a number of reasons, some of these firms may be unwilling or unable to remedy this defect. Third, some firms may not want to incur the reprogramming costs necessary to include electronic prescriptions for controlled substances capability in their service, and it is highly unlikely that a firm would try to stay in the market without controlled substances capability, as that would place it at a severe competitive disadvantage. A relevant point here is that most current firms offer electronic

health records (EHRs), with electronic prescription functionality as part of the EHR; the reprogramming costs may be much higher for firms that support only electronic prescriptions—just under $150,000 compared to a little under $40,000 for firms with EHR capability. To gain certification from CCHIT, EHR products must already include many of the security functions DEA is specifying in the proposed rule. Of the 119 vendors now in the market, 103 are EHRs. Those that are not EHRs are clearly more likely to be deterred by cost. DEA assumes that six of the electronic prescription-only vendors will withdraw from the market rather than add electronic controlled substances prescribing capability, while three of those that support EHR will also withdraw. Table 9 presents the service provider universe.

TABLE 9.—SERVICE PROVIDER UNIVERSE

Affected Universe—Service Providers		
	Current No.	Projection
Service providers to practitioners	119 Adjusted to 110	The number of firms is expected to diminish over time, stabilizing at 20 vendors after ten years.
Vendors to pharmacies (some are ASPs, most are not).	20	Provision of computer and Internet services to pharmacies is already a mature market segment; the number is not expected to change.

Unit Costs

In estimating unit costs of the rule, the first step is to establish the baseline with which to determine the costs that are incremental with respect to the rule. DEA presumes that no practitioner's office will adopt electronic prescribing simply to write controlled substance prescriptions; controlled substance prescriptions constitute about 11 percent of the total number of prescriptions. The costs to a practitioner's office of complying with the rule, therefore, are only the costs directly required by the electronic prescriptions for controlled substances rule and do not include any of the costs that the office would incur for setting up electronic prescription capability without electronic prescribing of controlled substances.

Requirements

- In-person identity proofing (§ 1311.105) imposes costs on practitioners, the institutions that conduct the identity proofing, and service providers (filing the information submitted and confirming the application).
- Two-factor authentication (§ 1311.110) requires that each practitioner with authority to sign controlled substance prescriptions has a unique hard token to gain access to the system. This imposes costs on some practitioners who do not already have a token (e.g., a PDA).
- Monthly review of controlled substance prescription logs (§ 1311.140) by practitioners imposes a cost on practitioners. (Applies only to Base Case and Option 1)
- System requirements (§§ 1311.110–1311.145) imposes reprogramming costs on service providers.
- Requirements (§ 1311.150) for annual third-party audits imposes costs on service providers.

Costs

Identity proofing. Identity proofing requires a face-to-face meeting between each practitioner who will use the system and either the service provider (Base Case) or a person from a DEA-registered hospital or other official (Options 1 and 2). For the Base Case, DEA assumes that the practitioner and service provider would spend 2 minutes each at the practice; the service provider would spend another 8 minutes at its offices checking the State license and DEA registration and filing the information gathered. Because most physicians have privileges at hospitals, DEA assumes that for Option 1 and 2 identity proofing would take only 10 minutes for physicians. All other practitioners are assumes to need an hour to travel to and from a hospital or police station plus the 10 minutes for the proofing. Each practitioner would also spend another 1 minute verifying the application when called by the provider. For each practitioner, the hospital staff are assumes to spend 10 minutes checking the identity documents and completing the form. The service provider will spend another 11 minutes at the service provider's office verifying State license and DEA registration information, entering the practitioner's data into the service provider's record of identity proofing, and calling the practitioner to verify. These costs are the same for Options 1 and 2, although under Option 2 the cross-signed identity proofing document would be sent to the Certification Authority.

Two-factor authentication. Two-factor authentication requires that access to the system can be gained only with a hard token, uniquely coded for each practitioner. A number of devices will serve for this purpose: *e.g.*, PDAs, Blackberries, thumb drives, multi-factor one-time-use password tokens. It is assumes that physicians and dentists will already have one of these devices and be familiar with its use. The same cannot be assumed for mid-level practitioners. DEA assumes that tokens will have to be purchased for 75.0 percent of mid-level practitioners and those mid-level practitioners will require training in the use of the tokens. DEA assumes that the tokens will be thumb drives. Time required for training is estimated to be ten minutes per mid-level practitioner. Using the hourly wages (including fringes and overhead) for physician's assistants for $77, the training cost is estimated to be $12.82. A thumb drive costs $12.00. One-time-password tokens may be more or less expensive; some of these can be installed on cell phones, which any practitioner would have.

Digital Certificate. Under Option 2, practitioners would be required to obtain a digital certificate from a certification authority cross-certified with a Federal Certification Authority. The annual cost of digital certificates varies from CA to CA depending on the security characteristics. DEA assumes an annual cost of $30.

Monthly review of controlled substance prescription logs. Under the Base Case and Option 1, once a month, each practitioner must review a log of his controlled substance prescriptions for that month. As discussed above, DEA is not proposing to require a comprehensive review. DEA estimates that a practitioner can review the log for unusual controlled substance prescriptions in an average of two minutes. DEA recognizes that there will be a considerable range in review time

based on the number of controlled substance prescriptions a practitioner writes. The average cost is estimated to be $89 per year, using a weighted hourly wage for all practitioners.

Reprogramming requirements. Under the Base Case, Option 1, and Option 2, all service providers, including those that serve pharmacies, will have to do some reprogramming to add electronic controlled substance prescription-required functions to their systems. Depending on the functionalities of their existing systems, they will need more or less reprogramming. Two requirements in particular will necessitate some reprogramming for almost all systems that serve practitioners. These are the provision that the first recipient system digitally sign and archive the controlled substance prescription on receipt and that the system will transmit from a practitioner's office immediately following the practitioner's signature with the hard token. (At least one service provider already digitally signs prescriptions, and more than one transmit the prescription immediately upon signature.) The requirement for a screen indicating that the prescriber understands that the prescription is being signed will also be new for systems. Other requirements will affect only some providers. Limiting access to signing to practitioners may require reprogramming of some systems, though this functionality is generally part of systems. The need to show all of the selected prescription information on a single screen may require new programming for a few systems. For some stand-alone systems, the requirements for two-factor authentication at Level 4 will require reprogramming as will requirements for reauthentication after a period of inactivity. As shown in the table of requirements in Section IX above, most EHRs already support these functions. Consequently, the reprogramming required for EHR systems will be less than for stand-alone systems.

Systems that serve pharmacies will also require some reprogramming, primarily for digitally signing the record as received. Those pharmacy systems that operate as ASPs should already have digital signature capability; others may need to do additional programming to add that functionality. Both will need to add programming to sign the record. The industry has indicated that the requirements for internal audit trails and internal audit analysis are part of existing systems.

DEA has estimated that EHR systems and pharmacy ASP systems will require an additional 500 hours to program and test the new functions. For stand-alone electronic prescription systems and installed pharmacy systems, DEA estimates that they will spend 2,000 hours to program and test the new functions. Using the hourly wage rate for programmers of $73 (loaded), the initial programming cost will be $36,700 for EHR and pharmacy ASP systems and $146,500 for stand-alone systems and installed pharmacy systems.

Auditing requirements. Under the Base Case, Option 1, and Option 2, all system providers that serve practitioners and those that serve pharmacies must undergo an annual third-party audit. Under the Base Case and Option 1, the audit would have to meet the requirements for a SysTrust, WebTrust, or SAS 70 audit for security and processing integrity. The first such audit for a service provider is generally more costly than subsequent audits. DEA estimates the following per-vendor costs for audits: First-year audits: $125,000; Subsequent audits: $100,000. Under Option 2, the audit would need to address only processing integrity (*i.e.*, that the system reliably meets DEA's requirements). Because of the limited scope of this audit, it could be conducted by a broader range of auditors; DEA estimates an annual cost of $25,000.

DEA notes that the costs of a SysTrust or SAS 70 audit range from $15,000 to $250,000 depending on the size of the company. DEA used a conservative estimate of $125,000 for the initial audit although in many cases the cost for the DEA required audit elements would be less. A full SysTrust or SAS 70 audit covers five areas; DEA is requiring that the audit address only two of those, physical security and processing integrity.

Callbacks. For Option 3, the only cost of electronic prescriptions for controlled substances would be the callback from the pharmacy to the practitioner to confirm the prescription. DEA estimates that this would take 3 minutes of staff time at the practitioner's office to pull the file and refile it, 1 minute of the practitioner's time, and 3 minutes of a pharmacy technician's time; the total cost per call would be $6.55.

Table 10 summarizes unit costs.

TABLE 10.—UNIT COSTS

Requirement	Unit time	Wage rate	Unit cost
Identity Proofing			
Practitioner (Base)	2 minutes	$222.51	$7.42
Service Provider (Base)	2 minutes	83.80	2.79
Service Provider clerk (Base)	8 minutes	33.89	4.52
Service Provider	10 minutes	33.89	5.65
Storage at service provider			0.01
Service Provider (1)	13 minutes	33.89	5.35
Practitioner (1 & 2):			
MDs	11 minutes	269.00	49.32
Dentists	11 minutes	214.07	39.25
Mid-level practitioners	11 minutes	76.94	14.11
Practitioner travel time:			
Dentists	1 hour	214.07	214.07
Mid-level practitioners	1 hour	76.94	76.94
Hospital	10 minutes	35.55	5.93
Mailing time	2 minutes	30.33	1.01
Mailing cost			0.41
Total—MDs (1 & 2)			62.32
Total—Dentists (1 & 2)			266.31
Total—Mid level practitioners (1 & 2)			104.05

TABLE 10.—UNIT COSTS—Continued

Requirement	Unit time	Wage rate	Unit cost
2-Factor Token			
Learning time	10 minutes	76.94	12.82
Token			12
Digital Certificate			30/year
Log review	24 minutes/year	222.51	89.01
Programming			
EHR/Pharmacy ASP	500 hours	73	36,623
Other systems	2,000 hours	73	146,490
Third-Party Audit (Base, 1)			125,000 (first year) 100,000 (following)
Third-Party Audit (2)			25,000 per year
Option 3:			
Callback	1 minute practitioner	222.51	6.55
	3 minutes med. staff	30.60	
	3 minutes pharmacy tech	26.23	

Total costs

To estimate total costs, it is first necessary to establish the distribution of costs over time. The costs to be considered in the analysis may be divided into start-up costs and ongoing costs. For a practitioner's office, the start-up costs are incurred in the year in which the office implements electronic prescribing of controlled substances, and the ongoing costs are incurred in every year thereafter. For service providers, all the start-up costs are incurred in Year 1 of the analysis. DEA presumes that all service providers will add controlled substance electronic prescribing capability to their systems in the first year, lest they be placed at a competitive disadvantage. But this will not be the case for practitioners' offices. They will implement electronic prescribing of controlled substances over time as they implement electronic prescriptions and EHRs. DEA has projected complete implementation of electronic prescribing of controlled substances over a 15-year period; i.e., at the end of the 15th year of the analysis, all practitioners' offices will have controlled substance electronic prescribing capability in their electronic prescription systems. This is essentially an estimate of the rate of electronic prescription implementation. As practitioners adopt electronic prescription capabilities, they will include electronic prescribing of controlled substances in the package, as the incremental cost of doing so for an office is very slight. DEA notes that although the selection of the implementation period is somewhat arbitrary, DEA believes that 15 years is a reasonable estimate to reflect the balance between pressure from insurers, who want practitioners to implement EHR systems, and the reluctance of practitioners to invest in expensive systems that are time-consuming to implement and perhaps not yet fully tested.

Table 11 shows the schedule at which DEA projects implementation over time.

TABLE 11.—IMPLEMENTATION SCHEDULE

	Percentage of offices implementing in a year	Cumulative implementation percentage
Year 1	6.0	6.0
Year 2	4.0	10.0
Year 3	4.0	14.0
Year 4	5.0	19.0
Year 5	5.0	24.0
Year 6	5.0	29.0
Year 7	6.0	35.0
Year 8	6.0	41.0
Year 9	7.0	48.0
Year 10	9.0	57.0
Year 11	10.0	67.0
Year 12	11.0	78.0
Year 13	11.0	89.0
Year 14	6.0	95.0
Year 15	5.0	100.0

The rate in Year 1 is somewhat higher than the rate in the next several years, because about 6 percent of offices have already adopted electronic prescription systems. After dropping in Year 2, the rate rises gradually to a peak in Years 12 and 13 and then drops as full implementation approaches. This is based on the observation that adoption of electronic prescribing has been slow to date and that many practitioners are very reluctant to accept changes in the basic methods with which they conduct their practices, especially the direct introduction of computer-based systems into their own work.

The start-up costs incurred by practitioners' offices in each year will be based on the number of practitioners in offices implementing controlled substances electronic prescribing capabilities in that year. Ongoing costs for practitioners will be based on the total number of practitioners in offices where electronic prescribing of controlled substances has been implemented in a given year, i.e., the cumulative percentage of practitioners in offices that have adopted electronic prescribing of controlled substances. Both start-up costs and ongoing costs will also reflect the annual growth rates of the different classes of practitioners—0.1 percent for physicians, 0.5 percent for dentists, and 2.2 percent for mid-level practitioners.

Start-up costs for practitioners are the initial identity proofing and the purchase of hard tokens, and training in their use, for some of the mid-level practitioners. The major ongoing cost under the Base Case and Option 1 is the monthly log review. But there is also some ongoing cost associated with turnover of personnel in practitioners' offices. When a practitioner moves to a new office, there is a high likelihood that the transfer will also be a move between system vendors; when that is the case, there must be a new identity proofing for that individual. Transfers of mid-level practitioners may require new purchases of hard tokens.

Some further assumptions beyond implementation and growth rates must be made to estimate total costs for practitioners' offices and service providers. These are as follows:

- For the Base Case, percentage of initial identity proofing visits by service provider staff where the travel to the office is needed only for the identity

proofing: 15.0 percent. (Percentage of non-EHR systems). For ongoing identity proofing visits due to personnel turnover, there is no incremental travel.

- Percentage of personnel transfers between offices that are also transfers between service providers: 90.0 percent.
- Annual turnover rate for physicians and dentists: 2.5 percent.
- Annual turnover rate for mid-level practitioners: 5.0 percent.

As noted earlier, the service providers will incur all their start-up costs, apart from identity proofing, in Year 1 of the analysis. Aside from identity proofing, their ongoing costs will be the annual audits. The cost per service provider will remain the same over time, but the total cost will diminish as the number of service providers serving practitioners declines in an ongoing process of attrition due to over-population on the supply side of the market. Although this reduction may seem large, DEA notes that in the mid-1980s, there were about 400 word processing software systems; only a few remain.[31] The number of service providers serving pharmacies remains stable at 20 throughout the analysis period. Table 12 shows DEA's projection of the number of providers serving practitioners.

TABLE 12.—PROJECTED REDUCTION IN ELECTRONIC PRESCRIPTION SERVICE PROVIDERS

	Number of providers serving practitioners
Year 1	110
Year 2	95
Year 3	80
Year 4	70
Year 5	60
Year 6	50
Year 7	40
Year 8	30

TABLE 12.—PROJECTED REDUCTION IN ELECTRONIC PRESCRIPTION SERVICE PROVIDERS—Continued

	Number of providers serving practitioners
Year 9	25
Year 10	25
Year 11	20
Year 12	20
Year 13	20
Year 14	20
Year 15	20

The results of the unit costs and the foregoing assumptions about distribution of costs over time and other items are summarized in Tables 13 and 14, showing the annualized cost, over 15 years at a 7 percent and a 3 percent discount rate. Table 15 presents a summary of annualized costs for the four options.

TABLE 13.—ANNUALIZED COST PER OPTION AND REQUIREMENTS

[7% Discount rate]

	Practitioners	Providers	Total
	Base Case 7.0 percent		
Identity Proofing	$352,367	$459,425	$811,792
Tokens	90,757		90,757
Training	75,147		75,147
Log reviews	22,495,039		22,495,039
Reprogramming		824,224	824,224
Audits		8,264,492	8,264,492
Total			32,561,452
	Option 1		
Identity Proofing	6,151,445	354,910	6,506,355
Tokens	90,757		90,757
Training	75,147		75,147
Log reviews	22,495,039		22,495,039
Reprogramming		824,224	824,224
Audits		8,264,492	8,264,492
Total			38,256,015
	Option 2		
Identity Proofing	6,151,445	354,910	6,506,355
Tokens	90,757		90,757
Training	75,147		75,147
Digital Certificates	7,582,154		7,582,154
Reprogramming		703,606	703,606
Audits		3,636,812	3,636,812
Total			18,594,831
	Option 3		
Callbacks	1,023,778,891	256,261,645	1,280,040,536

[31] Bergin, T.J., ''The Proliferation and Consolidation of Word Processing Software: 1985–1995.'' *IEEE Annals of the History of Computing.* Volume 28, Issue 4, Oct.–Dec. 2006 Page(s):48–63.

TABLE 14.—ANNUALIZED COST PER OPTION AND REQUIREMENTS

[3% Discount rate]

	Practitioners	Providers	Total
	Base Case 3.0 percent		
Identity Proofing	$357,789	$443,823	$801,612
Tokens	94,227		94,227
Training	76,832		76,832
Log reviews	24,389,580		24,389,580
Reprogramming		628,833	628,833
Audits		7,401,186	7,401,186
Total			33,392,270
	Option 1		
Identity Proofing	6,269,439	360,851	6,630,290
Tokens	94,227		94,227
Training	76,832		76,832
Log reviews	24,389,580		24,389,580
Reprogramming		628,833	628,833
Audits		7,401,186	7,401,186
Total			39,220,948
	Option 2		
Identity Proofing	6,269,439	360,851	6,630,290
Tokens	94,227		94,227
Training	76,832		76,832
Digital Certificates	8,220,726		8,220,726
Reprogramming		536,808	536,808
Audits		3,369,812	3,369,812
Total			18,928,003
	Option 3		
Callbacks	1,123,085,458	281,119,029	1,404,204,487

TABLE 15.—TOTAL ANNUALIZED COSTS

	7.0 percent	3.0 percent
Base Case	$32,561,000	$33,392,000
Option 1	38,256,000	39,221,000
Option 2	18,595,000	18,928,000
Option 3	1,280,041,000	1,404,205,000

The two largest cost drivers for the Base Case are the monthly log review for practitioners and the annual audits for the service providers. The cost for practitioners almost disappears without the log review; with the 7.0 percent interest rate, it drops to under $1.0 million. The annual audits account for approximately $8 million of the cost to service providers at the 7.0 percent rate. For Options 1 and 2, identity proofing is a significant cost; these costs fall mainly on practitioners who do not routinely visit hospitals as part of their practices. For Option 2, digital certificates are also a significant cost, but audits are a lower cost. Option 3 is far more costly than any of the other options although it entails no upfront costs and imposes no costs on the service providers.

Benefits

The benefits often ascribed to electronic prescriptions are not directly attributable to this rule except to the extent the rule facilitates implementation of electronic prescribing. Electronic prescriptions may provide benefits to patients by reducing medication errors caused by illegible or misunderstood prescriptions. They may also reduce processing time at the pharmacy, callbacks to practitioners, and waiting time for patients. To estimate the part of these benefits that may accrue to the proposed rule, DEA estimated the number of controlled substance prescriptions that may require callbacks (approximately 27 percent of original prescriptions). Assuming that electronic controlled substance prescriptions phased in over 15 years, as described above, the annualized time-saving for eliminating these callbacks would be $316 million (at 7% discount) or $346 million (at 3% discount). Electronic prescriptions could also reduce the patient's wait time at the pharmacy. Assuming the average wait time is 15 minutes for the 81 percent of original prescriptions that are presented on paper to retail pharmacies (not mail order or long-term care prescriptions), at the current United States average hourly wage ($19.62), the annualized savings over 15 years would be $589 million (at 7% discount) or $646 million (at 3%

discount). The estimates for public wait time are upper bounds. They assume that the practitioner will transmit the prescription and that the pharmacist will open the record and fill it before the patient arrives at the pharmacy. It is probably more realistic to assume that only a fraction of these benefits will be gained. There may also be some offsetting costs to the pharmacy. The industry estimates that about 20 percent of prescriptions written are never presented to pharmacies. If these are sent to pharmacies electronically and prepared before the patient arrives, the pharmacy will have spent time for which it will not be reimbursed if the patient does not pick up the prescription. (It may be reasonable to expect the 20 percent to decline with electronic prescriptions, although probably not to zero.) Table 16 presents the annualized benefits at a 7 percent and 3 percent discount rate.

TABLE 16.—ANNUALIZED BENEFITS

	7.0 percent	3.0 percent
Callbacks Avoided	$315,626,000	$346,242,000
Public Wait Time Avoided	588,732,000	645,839,000

The benefits, both of which represent time savings, clearly exceed by a wide margin the costs of the Base Case and Options 1 and 2. The costs of Option 3 at $1.3 to $1.4 billion a year exceed the benefits, which would not, of course, include callbacks eliminated.

Other Benefits. DEA has not attempted to quantify any reduction in medical errors. Most of the studies on medication errors have been done in hospital settings; the studies of outpatient errors do not usually disaggregate the types of errors to distinguish those that could be prevented by accurate electronic prescriptions (e.g., misread illegible prescriptions versus a dispensing error such as inadvertently selecting the wrong drug or wrong strength); and none indicate what percentage of errors are related to controlled substances. In addition, although electronic prescriptions should eliminate illegibility issues, some of these mistakes may be replaced by keying errors. DEA expects that there will be reduced medication errors linked to more readable prescriptions, but decided that it did not have a reasonable basis for quantifying the benefits.

Another benefit of electronic prescriptions for controlled substances that is ascribable to the proposed rule, but not easily quantified and monetized, would come from reductions in controlled substance prescription forgery and alteration. Prescription forgery, alteration, and misuse (e.g., faxing the same prescription to multiple pharmacies) is a part of the total illegal market for diversion of legal drugs. Diversion of legal medication for illegal consumption usually involves controlled substances. Diversion and abuse are significant social problems; the proposed rule is intended to help curb some of these illegal activities.

As discussed above, diversion of prescription drugs through forgery, doctor shopping, and alteration of pharmacy records is a growing problem. Controlled substances are diverted in a number of ways, some of which will not be affected by electronic prescriptions. For example, diversion occurs when:

- Drugs are stolen from practitioners and pharmacies.
- Practitioners knowingly write nonlegitimate prescriptions.
- Practitioners write prescriptions for people who have lied about symptoms to obtain the drugs. A commonly used term for these types of patients is ''doctor shoppers,'' people who routinely visit different doctors with the same ailment to obtain multiple prescriptions for controlled substances, usually pain relievers. These prescriptions are then filled at various pharmacies and the drugs are abused or sold on the illicit market.

Although DEA does not expect this rule to eliminate these problems, it may act as a deterrent to practitioners who write nonlegitimate prescriptions and to doctor shoppers because it will be easier for States that have prescription monitoring programs to monitor prescriptions when they are electronic and because digitally signed prescriptions will make it very difficult for a practitioner to claim that a digitally signed prescription has been forged or altered. Some States are already using prescription monitoring programs to identify practitioners who prescribe unusual quantities of controlled substances and patients filling multiple prescriptions at different pharmacies.

Electronic prescriptions for controlled substances will directly affect the following types of diversion:

- Stealing prescription pads or printing them, and writing nonlegitimate prescriptions.
- Altering a legitimate prescription to obtain a higher dose or more dosage units (e.g., changing a ''10'' to a ''40'').
- Phoning in nonlegitimate prescriptions late in the day when it is difficult for a pharmacy to complete a confirmation call to the practitioner's office.
- Faxing a prescription to multiple pharmacies.
- Altering a pharmacy record to cover the diversion of controlled substances.

These are examples of prescription forgery that contribute significantly to the overall problem of drug diversion. DEA expects this rule to reduce significantly these types of forgeries because only practitioners with secure prescription-writing systems will be able to issue electronic prescriptions for controlled substances and because any alteration of the prescription at the pharmacy will be discernible from the audit log and a comparison of the digitally signed records. DEA expects that over time, as electronic prescribing becomes the norm, practitioners issuing paper prescriptions for controlled substances may find that their prescriptions are examined more closely.

DEA is not aware of any comprehensive data on controlled substance prescription diversion in general, and forgeries in particular. DEA does not track information on prescription forgeries and alterations because enforcement is generally handled by State and local authorities. The cost of enforcement is, however, considerable. In 2007, DEA spent between $2,700 for a small case and $147,000 for a large diversion case just for the primary investigators; adjudication costs and support staff are additional. It is reasonable to assume that State and local law enforcement agencies are spending similar sums per case. As discussed above, some cases involve multiple jurisdictions, all of which bear costs for collecting data and deposing witnesses. The rule as proposed could reduce the number of cases and, therefore, reduce the costs to governments at all levels. A reduction in forgeries would also benefit practitioners who would be less likely to be at risk of being accused of diverting controlled substances and of then having to prove that they were not

responsible. In contrast, a less secure electronic prescription system could greatly increase diversion and the number of forgeries and diversion cases and dramatically increase investigation costs if every provider and intermediary involved in a transaction had to provide testimony.

A reduction in forged controlled substance prescriptions could also result in a reduction in drug addiction-related deaths, injuries, and crime. The 2006 NSDUH found that 6.7 million people in the United States currently use prescription-type therapeutic drugs for nonmedical reasons. SAMHSA reported that in 2003, in six States (Maine, Maryland, New Hampshire, New Mexico, Utah, and Vermont) there were 352 deaths from misuse of oxycodone and hydrocodone, both prescription controlled substances.[32] The 32 metropolitan areas that are part of the Drug Abuse Warning Network reported 3,530 deaths from misuse of oxycodone and hydrocodone and 1,381 deaths that involved the misuse of benzodiazepines in 2003.[33] In another report, SAMHSA stated that in 2004 there were 42,491 emergency room visits involving nonmedical use of hydrocodone, 36,559 visits for nonmedical use of oxycodone, and 144,000 visits for nonmedical use of benzodiazepines (Schedule IV).[34] By 2005, the number of emergency visits for nonmedical use of these drugs rose to 51,225 for hydrocodone, 42,810 for oxycodone, and 172,388 for the benzodiazepines. For all non-medical use of prescription opiates except methadone, the number of visits was about 155,000.[35] The costs of the deaths in the six States is more than $1 billion (at $3 million per life) and in the metropolitan areas more than $10 billion. The cost of the emergency room visits is above $300 million (at $1,000 per visit). A recent study of drug diversion and insurance fraud estimated that drug diversion costs health insurers $72 billion a year because of claims for fraudulent prescriptions and treating patients for the effects of drug abuse.[36] If the proposed rule prevents even a small fraction of these costs, the benefits will far exceed the implementation costs.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612) (RFA), Federal agencies must evaluate the impact of rules on small entities and consider less burdensome alternatives. DEA has conducted an initial Regulatory Flexibility Analysis and concluded that although the rule will affect a substantial number of small entities, it will not impose a significant economic impact on any regulated entities. The only entities regulated by DEA under this rule would be DEA registrants—prescribing practitioners and pharmacies. The service providers, although indirectly affected by the rule, are not registrants. Under the proposed rule, service providers may design and implement their systems and services in any way they choose. A DEA registrant, however, may not use a system that does not meet the requirements of the rule to create, transmit, receive, or process a controlled substance prescription. Nothing in this rule compels a DEA registrant to issue or process controlled substance prescriptions electronically. Practitioners may continue to issue controlled substances prescriptions on paper and, where permitted, by fax or telephone. Besides being only indirectly affected by the rule, the service providers are expected to recover their costs from registrants and others who purchase the software and systems.

Characteristics of Small Entities

As discussed in previous sections, the small entities directly affected by the proposed rule are practitioners and to a limited extent pharmacies. The firms marketing services and software are not directly affected by the rule because they will recover their costs from practitioners. Nonetheless, DEA will discuss the impact on these firms. Table 17 shows Small Business Administration's standards for these firms.

TABLE 17.—SBA DEFINITIONS OF SMALL ENTITIES

Affected entity	Industry description	NAICS code	Small business definition (sales in $)
Practitioner and Mid-Level Practitioner	Offices of Physicians	62111	$9,000,000
	Offices of Dentists	621210	6,500,000
Service Provider	Software Publishing	511210	23,000,000
Pharmacy	Pharmacies and Drug Stores	44611	6,500,000
	Supermarkets and Other Grocery Stores	44511	25,000,000
	General Merchandise Stores	45291	25,000,000
	Mail Order Houses	454113	23,000,000

Although some practitioners are part of large practices that may qualify as large businesses, so few practitioners fall into the large category that it is simpler to assume that they are all small entities. It is also the case that the service providers generally charge on a per practitioner basis rather than a per practice basis so that the costs may be considered as applying to individual practitioners. Mid-level practitioners are generally employed by a practice so their costs would be incurred by the practice, not the individual. They are not, therefore, small businesses.

The lowest average net income for a physician in private practice listed in the Allied-Physician Survey is $135,000.[37] The American Dental Association states that the average net

[32] The New DAWN Report—Opiate-related Drug Misuse Deaths in Six States, 2003. Issue 19, 2006; *http://dawninfo.samhsa.gov/pubs/shortreports/*.

[33] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Drug Abuse Warning Network, 2003: Area Profiles of Drug-Related Mortality*. DAWN series D–27, DHHS Publication No. (SMA) 05–4023, Rockville, MD, March 2005; *http://dawninfo.samhsa.gov/pubs/mepubs/*.

[34] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. The DAWN Report—Emergency Department Visits Involving Nonmedical Use of Selected Pharmaceuticals. Issue 23, 2006; *http://dawninfo.samhsa.gov/pubs/shortreports/*.

[35] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Drug Abuse Warning Network, 2005: National Estimates of Drug-Related Emergency Department Visits.* DAWN Series D–29, DHHS Publication No. (SMA) 07–4256, Rockville, MD, March 2007; *http://dawninfo.samhsa.gov/pubs/edpubs/default.asp.*

[36] Coalition Against Insurance Fraud, ''Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs,'' December 2007.

[37] *http://www.allied-physicians.com/salary-surveys*, accessed 1/16/2008.

income of a dentist in private practice is $185,940 for a general practitioner. The average gross billings for a dentist in general practice per dentist is $595,340.[38] For pharmacies, the 17,500 independent pharmacies are small entities; the other pharmacies belong to about 200 chains that are mostly large firms. There may be a few chains with fewer than 3 pharmacies, which could be small. In 2006, National Association of Chain Drug Stores data indicate that the average independent pharmacy had prescription sales of $2.48 million a year; average total sales are about $2.675 million.[39]

As discussed above, DEA estimates that there are about 130 service providers (110 for electronic prescriptions, 20 for pharmacies) that will be indirectly affected by this rule. A few of these are large entities or part of large companies (e.g., General Electric and McKesson). DEA has no information on the revenues of most of these firms. DEA notes that fully electronic EHRs cost between $20,000 and $50,000 per practitioner, with a usual monthly maintenance fee of $500 per practitioner. A provider, therefore, would need fewer than 4,000 practitioners to qualify as a large business. The providers of stand-alone electronic prescribing systems charge a tenth as much and are assumed to be small entities.

Costs to Small Entities

The costs to DEA registrants are relatively small. As noted above, the initial costs to the practitioner would range from about $62 to $266 for identity proofing, mostly for the time to have the identification checked. The main ongoing costs for the proposed rule would be the monthly log review by practitioners (about $89 a year) plus any incremental cost of the software or service. The initial and ongoing costs for the basic rule elements represent less than 0.2 percent of the annual income of the lowest paid practitioner.

Determining the incremental cost of the system requirements per practitioner is difficult because it depends on the number of providers, the number of customers, the number of system requirements that a service provider does not already meet, and how costs are recovered (in the year in which the money is spent or over time). For example, an EHR system that had to reprogram to the full extent would have incremental system costs of $161,000 ($125,000 for the third-party audit and $37,000 for reprogramming). If the service provider had 1,000 practitioners enrolled in the first year, it would also incur about $5,660 for identity proofing. If the service provider recovered the costs ($167,000) from its 1,000 customers, the incremental cost to those customers would be $167 or about $14 a month. The costs in the out years would be lower because no further programming is needed and the audit cost is lower ($100,000). If the service provider added 1,000 practitioners a year over 15 years, the incremental cost per practitioner would fall as shown in Table 18. The costs shown are conservative because the audits may cost considerably less depending on the complexity of the system; many EHRs may need little reprogramming. Either or both of these factors in combination could reduce their costs considerably and, therefore, reduce the incremental costs to practitioners.

TABLE 18.—INCREMENTAL COST OF EHR SYSTEMS TO PRACTITIONERS

Year	No. Practitioners	Total provider costs	Annual cost/practitioner	Monthly cost/practitioner
1	1000	$167,70	$167.27	$13.94
2	2000	105,648	52.82	4.40
3	3000	105,648	35.22	2.93
4	4000	105,648	26.41	2.20
5	5000	105,648	21.13	1.76
6	6000	105,648	17.61	1.47
7	7000	105,648	15.09	1.26
8	8000	105,648	13.21	1.10
9	9000	105,648	11.74	0.98
10	10000	105,648	10.56	0.88
11	11000	105,648	9.60	0.80
12	12000	105,648	8.80	0.73
13	13000	105,648	8.13	0.68
14	14000	105,648	7.55	0.63
15	15000	105,648	7.04	0.59

In the first year, the total cost to a physician for DEA's requirements would be less than $300; dentists would have higher initial costs because of travel time. After that, the cost will decline over time to about $100 to $150 a year including the incremental costs charged for the systems. The lowest paid physician earns about $135,000 a year. For none of the registrants will the cost represent a significant economic impact.

For pharmacies, the only costs will be the incremental cost that their service provider charges to cover the costs of reprogramming and audits. In the first year, if the service providers recover the programming costs in a single year, the average incremental cost to a pharmacy would be $85. After that, the incremental charge to recover the cost of the third-party audit would be $35 per pharmacy, assuming the cost is evenly distributed across all pharmacies. The first year charge represents 0.003 percent of an independent pharmacy's annual sales. It also represents a far lower cost than the pharmacy will pay SureScripts or another intermediary for processing the prescriptions. Currently, SureScripts charges the pharmacy $0.215 per electronic prescription to process and reformat prescriptions to ensure that the pharmacy system will be able to capture the data electronically. Based on National Association of Chain Drug Stores data on the average price of prescriptions ($68.26) and the average value of prescription sales, an independent pharmacy processes about 36,400 prescriptions a year and would have to pay SureScripts about $7,800.[40]

[38] *http://www.ada.org/ada/prod/survey/faq.asp*, accessed 1/16/2008.

[39] *http://www.nacds.org/wmspage.cfm?parm1=507*, accessed 1/18/2008.

[40] *http://www.nacds.org/wmspage.cfm?parm1=507*, accessed 1/18/2008.

Although these costs do not represent a significant economic impact, as discussed above, DEA considered options. The Base Case option would be less expensive initially, particularly for dentists and mid-level practitioners, because much less time would be needed for identity proofing. Once the identity proofing has occurred, however, the costs would be the same for the Base Case and Option 1. Option 2 would be less expensive for practitioners because the monthly log check would not be needed and the service provider costs would be lower because less stringent auditing requirements would be imposed. DEA has not proposed the Base Case because of two concerns about identity proofing. First, DEA is concerned that having a service provider employee checking the documents would make it easier for insider collusion to occur. Putting the in-person identity proofing in the hands of a DEA registrant or a public employee lessens that threat. Second, others expressed a concern that service providers would not visit practitioners' offices often, which could delay implementation and adoption, particularly for rural practices. DEA is not proposing the PKI option except for Federal health care agencies because of the concerns expressed by industry with regard to the use of digital signatures and the problems they would create for intermediaries. The third option, which would impose no costs on service providers, would be very expensive for pharmacies and practitioners. If the average independent pharmacy processes 36,400 prescriptions, about 11 percent of those are likely to be for controlled substances. Their annual cost for conducting callbacks on each of those would be about $5,200 in 2008; eliminating callbacks that already occur, the costs would be about $3,800 in 2008. If the number of controlled substance prescriptions (359 million original and newly authorized refills in 2008) were equally distributed among practitioners (about 573,000 in 2008), the average practitioner would incur costs of about $3,300 for callbacks under Option 3. Eliminating the callbacks that already occur, the average practitioner would incur new costs of about $2,200 under Option 3.

DEA has, therefore, determined that the proposed rule would not impose a significant economic impact on a substantial number of small entities directly subject to the rule. Less expensive options are considered too burdensome by the service providers and intermediaries. The option that would impose no burden on service providers would impose substantially higher costs on practitioners and pharmacies.

Another issue that DEA considered is whether the incremental costs might affect practitioners' decisions about purchasing a system that provides electronic prescribing. As discussed in previous sections of this preamble, the market for these systems has shifted away from stand-alone systems to EHRs. The cost of an EHR system for the functionalities that CCHIT requires ranges from $20,000 to $50,000 per practitioner with a usual annual maintenance charge of $6,000 per practitioner. (There are some less expensive systems marketed as EHRs that have only some of the functions; some appear to provide billing, scheduling, and simple records, but none of the more complex functions such as electronic prescribing, database links, etc.) Even in the first year, where the incremental cost of adding DEA's requirements would be between $150 and $200, this additional charge is unlikely to affect the decision to invest in an EHR, where the first year cost would be, at the low end $26,000 ($20,000 plus the $6,000 maintenance fee). The incremental costs would add less than 1 percent of the cost of the system; in the out-years, the incremental costs would similarly be a small fraction of the annual system maintenance cost. For stand-alone electronic prescription systems, the initial incremental costs will be higher because they are expected to need more programming. After the initial year, however, their incremental costs should be similar. These costs will represent a greater percentage increase in their monthly charges, which average $50 per month, but this is unlikely to affect the initial decision of whether to adopt electronic prescribing systems because most of these systems are being provided free to practitioners by insurers that want to encourage electronic prescribing.

DEA considers it unlikely that any service provider would attempt to market a product or service that could not be used for controlled substance records and, therefore, no service provider will be disadvantaged by complying because all service providers will incur costs and recover them from customers. The situation may be similar to certification of EHRs by CCHIT. Some were concerned that the standards would create barriers, but most of the companies certified have been small. The chairman of CCHIT, Mark Leavitt, stated that the data on the revenues of firms that gained certification ''laid to rest this concern that it was going to squeeze out small vendors. It actually seems to have done the opposite. It's created a level playing field.'' [41]

DEA notes that the barriers to adoption of electronic prescribing cited in various government studies relate to the high cost of the systems, the disruption caused by implementing these systems, and the relatively early stage of system development and interoperability provided by the existing systems. Despite the benefits of legible prescriptions, both in terms of patient safety and fewer callbacks from pharmacies, practitioners have resisted adoption of electronic prescriptions. Insurance companies that have offered the systems for free have had difficulty finding practitioners willing to accept them because while the service is free, the cost of additional hardware, training, and staff disruption is a barrier to adoption. In 2005, Wellpoint offered physicians $42 million in hardware, software, and support. ''Of the 25,000 physicians contacted, only 19,000 accepted these free gifts,'' Wellpoint then-CEO Leonard Schaeffer said. ''And of those 19,000, only 2,700 physicians chose e-prescribing PDAs. The rest selected a paperwork reduction package. * * * Free is not cheap enough,'' Schaeffer concluded.[42] The likelihood that the electronic prescribing systems will be part of EHR systems probably is also slowing adoption because practices do not want to invest in a stand-alone system that will be redundant later.

A study of physicians' experiences with commercial electronic prescription systems that was funded by HHS and published in Health Affairs on April 3, 2007, examined the implementation of electronic prescribing.[43] The study focused on larger medical practices (12 of the 21 practices had more than 50 doctors; none had fewer than 5), which meant that many of the practices had IT staff and support. Many of the problems encountered involved not the basic function of writing a prescription, but other functions that are designed to improve patient safety (e.g., medication histories, clinical decision support) and formulary compliance. Connectivity with pharmacies was also a problem.

[41] California HealthCare Foundation, ''Gauging the Progress of the National Health Information Technology Initiative: Perspectives from the Field.'' January 2008.

[42] Schaeffer, L. WellPoint Health Networks, Thousand Oaks, CA. Transforming an IT-Enabled Health Care System: The Health Plan Role. Presentation at the Second Annual National Health Information Summit. Washington DC, October 20, 2004. *http://www.managedcaremag.com/archives/0504/0504.pharmacy.html.*

[43] Grossman, Joy M. *et al.*, ''Physicians' Experiences Using Commercial E-Prescribing Systems,'' *Health Affairs*, 26, no. 3 (2007), w393–w404.

Practice estimates of the number of prescriptions printed out for the patient ranged from 10 percent to close to 100 percent. Despite the theoretical level of pharmacy readiness for electronic prescriptions, ''most practices using electronic fax or EDI [electronic data interchange] reported spending substantial time educating pharmacies about e-prescribing.'' Many practices noted that ''at least some of the mail-order PBMs [pharmacy benefit managers] routinely rejected prescriptions sent via electronic fax or EDI* * *''

Implementing a system was reported to be very complicated. One physician reported working with the IT department 4 hours a week for 6 months to iron out the ''kinks'' in the electronic prescribing module before the system could be tested. Maintenance of the system continued to demand staff resources. The study concluded:

> Much of the literature assessing barriers to electronic prescribing adoption and use has focused on cost, physician resistance, and changing practice workflow. Our findings highlight the role of product limitations, external implementation challenges, and physicians' preferences for how to use system features and are consistent with several other assessments of e-prescribing system functionality and provider pharmacy connectivity.
>
> Respondents' implementation hurdles belie the view that electronic prescribing products are relatively simple ''plug-and-play'' applications. It is hard to imagine that e-prescribing as it exists today can be the ''killer app'' that will drive further IT adoption. All of the practices we examined, regardless of size, IT expertise, geographic location, or vendor, had invested many financial and human resources in implementing and maintaining e-prescribing.

These findings are consistent with the CDC study cited above, which found that electronic prescribing was one of the less used functions in a fully or partially electronic EMR system.[44]

Creating an electronic prescription takes more time than writing a paper prescription and handing it to a patient. The electronic prescription system shifts some responsibility from the pharmacy to the practitioners. At present, it is the pharmacy that checks to see if a particular drug is covered by the patient's insurance and that checks for drug interactions by examining other medications the patient is taking. With electronic prescriptions, all of these checks may occur before the practitioner signs the prescription. While this process may significantly reduce processing time at the pharmacy and ensure that more prescribed drugs are on the insurance companies' formularies, it may substantially increase the time a practitioner must spend to create a prescription. Rather than spending a few seconds writing a prescription while talking to the patient, the practitioner has to move through a series of drop-down menus to select the patient, drug, dosage unit, and directions, then determine whether the insurance company will cover it and at what level of co-pay. Finally the practitioner will have to find the pharmacy from a drop-down menu. Electronic prescriptions are likely to save practices staff time in reduced callbacks, but the practitioners may initially see mainly the additional time that needs to be spent creating the prescription and the office disruption that occurs when staff need to be trained on new systems. (An earlier Rand study noted that although electronic prescriptions will eliminate errors caused by misread or misunderstood prescriptions, practitioners may not review the prescription to check that the right items from successive menus have been selected. Electronic prescriptions may introduce new errors through system design flaws. They may also reduce the likelihood that the pharmacy will check the prescription for errors.)[45]

DEA recognizes that the rule could potentially impose a burden on service providers, but the costs are not so great that a service provider would not be able to recover them from customers or that the incremental price increase would discourage customers from purchasing a system. The programming that may be needed to implement a conforming system is not so onerous that a service provider would find it a significant burden; designing and programming systems is what these companies do. The cost of the annual third-party audit may be burdensome, but without the audit there is no assurance that the system is protected against identity theft and insider attacks, two of the most likely sources of diversion. DEA expects that some service providers may drop out of the market if they cannot meet the security standards that an auditor would demand, but given other government requirements for security under HIPAA and the public's expectations for secure medical records, DEA believes that these providers would not be able to meet other standards and public expectations. The market for healthcare IT is evolving rapidly. As discussed above, DEA anticipates that most of the current providers will not be in this market by the time most practitioners have adopted EHR systems. Eventually, for reasons unrelated to DEA, a few systems will dominate the market; for these service providers, DEA's requirements will not be a burden.

Further information on small business costs is included in the *Initial Economic Impact Analysis of the Electronic Prescriptions for Controlled Substances Rule*.

Paperwork Reduction Act

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection request to the Office of Management and Budget for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Comments regarding the information collection-related aspects of this proposed rule should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

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

[44] Centers for Disease Control and Prevention, ''Electronic Medical Record Use by Office-Based Physicians and Their Practices: United States 2006.'' *Advance Data from Vital and Health Statistics*, Number 393, October 26, 2007.

[45] Bell, D.S. *et al.*, ''Recommendations for Comparing Electronic Prescribing Systems: Results of An Expert Consensus Process,'' *Health Affairs*, May 25, 2004, W4–305–317.

e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Recordkeeping for electronic prescriptions for controlled substances.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:*

Form number: None.

Office of Diversion Control, Drug Enforcement Administration, Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Business or other for-profit.

Other: None.

Abstract: DEA would require that a DEA-registered hospital, State board, or law enforcement agency check a government-issued photographic identification. The practitioner would mail the signed document that the identification check has occurred to the service provider, which would be required to check the validity of a registrant's DEA registration and State license and retain a record of the check. The service provider would also be required to contact the practitioner by phone to verify the submission. DEA would require practitioners to review, on a monthly basis, a log of controlled substance prescriptions they have written and indicate that they have done so. The service provider would be required to retain a record that the log was reviewed and would be required to retain a digitally signed copy of the prescription as transmitted. Pharmacy systems would be required to digitally sign and archive the prescription as received. All service providers would be required to post a copy of the report of an annual third-party audit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

Over the three years of this information collection request, DEA estimates that a maximum of 110 electronic prescription service providers, 20 pharmacy service providers, and 81,000 practitioners will comply with this proposed rule. The practitioners are estimated to spend 11 minutes for identity proofing, 2 minutes for mailing, and 24 minutes a year for log review. The entity conducting the in-person identity proofing would spend 10 minutes for identity proofing. Service providers would spend 13 minutes on identity proofing per practitioner. They will also spend 500 hours (for EHR and pharmacy ASP systems) or 2,000 hours (for stand-alone electronic prescription and installed pharmacy systems) in the first year programming the systems to meet the requirements. No costs are associated with digitally signing or retaining electronic records. These functions are handled by computers; service providers already retain prescription records as part of normal business practices.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 211,000 hours over three years, an average of 70,200 hours per year.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Congressional Review Act

It has been determined that this rule is a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule is voluntary and could result in a net reduction in costs. This rule will not result in a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the net expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year and will not significantly or uniquely affect small governments. Because this proposed rule will not affect other government, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995. The economic impact on private entities is analyzed in the *Draft Economic Impact Analysis of the Proposed Electronic Prescription Rule*. Cost savings will exceed direct costs.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1306

Drug traffic control, Prescription drugs.

21 CFR Part 1311

Administrative practice and procedure, Certification authorities, Controlled substances, Digital certificates, Drug traffic control, Electronic signatures, Prescription drugs, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR parts 1300, 1304, 1306, and 1311 are proposed to be amended as follows:

PART 1300—DEFINITIONS

1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

2. Section 1300.03 is added to read as follows:

§ 1300.03 Definitions relating to electronic orders for controlled substances and electronic prescriptions for controlled substances.

Audit means an independent review and examination of records and activities to assess the adequacy of system controls, to ensure compliance with established policies and operational procedures, and to recommend necessary changes in controls, policies, or procedures.

Audit Trail means a record showing who has accessed an information technology system and what operations the user performed during a given period.

Authentication means verifying the identity of the user as a prerequisite to allowing access to the information system.

Authentication protocol means a well specified message exchange process that verifies possession of a token to remotely authenticate a prescriber.

Biometric authentication means authentication based on measurement of the individual's physical features or repeatable actions where those features or actions are both unique to the individual and measurable.

Cache means to download and store information on a local server or hard drive.

Certificate Policy means a named set of rules that sets forth the applicability of the specific digital certificate to a particular community or class of application with common security requirements.

Certificate Revocation List (CRL) means a list of revoked, but unexpired certificates issued by a Certification Authority.

Certification Authority (CA) means an organization that is responsible for verifying the identity of applicants, authorizing and issuing a digital certificate, maintaining a directory of public keys, and maintaining a Certificate Revocation List.

CSOS means controlled substance ordering system.

Digital certificate means a data record that, at a minimum—

(1) Identifies the certification authority issuing it;

(2) Names or otherwise identifies the certificate holder;

(3) Contains a public key that corresponds to a private key under the sole control of the certificate holder;

(4) Identifies the operational period; and

(5) Contains a serial number and is digitally signed by the Certification Authority issuing it.

Digital signature means a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed.

Digitally sign means to affix a digital signature to a data file.

Electronic prescription means a prescription that is generated on an electronic system and transmitted as an electronic data file. An electronic prescription must comply with the requirements of parts 1306 and 1311 of this chapter. A prescription generated on an electronic system that is printed out or transmitted via facsimile to a pharmacy is not considered to be an electronic prescription and must be manually signed.

Electronic signature means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message.

FIPS means Federal Information Processing Standards. These Federal standards, as incorporated by reference in § 1311.08 of this chapter, prescribe specific performance requirements, practices, formats, communications protocols, etc., for hardware, software, data, etc.

FIPS 140–2, as incorporated by reference in § 1311.08 of this chapter, means a Federal standard for security requirements for cryptographic modules.

FIPS 180–2, as incorporated by reference in § 1311.08 of this chapter, means a Federal secure hash standard.

FIPS 186–2, as incorporated by reference in § 1311.08 of this chapter, means a Federal standard for applications used to generate and rely upon digital signatures.

Hard token means a cryptographic key stored on a special hardware device (e.g., a PDA, cell phone, smart card) rather than on a general purpose computer.

Identity Proofing means the process by which a service provider validates sufficient information to uniquely identify a person.

Intermediary means any technology system that receives and transmits an electronic prescription between the practitioner and pharmacy.

Key pair means two mathematically related keys having the properties that (1) one key can be used to encrypt a message that can only be decrypted using the other key and (2) even knowing one key, it is computationally infeasible to discover the other key.

NIST means the National Institute of Standards and Technology.

NIST SP–800–63, as incorporated by reference in § 1311.08 of this chapter, means a Federal standard for electronic authentication.

Paper prescription means a prescription created on paper or computer generated to be printed or transmitted via facsimile that meets the requirements of part 1306 of this chapter including a manual signature.

PDA means a Personal Digital Assistant, a handheld computer used to manage contacts, appointments, and tasks.

Private key means the key of a key pair that is used to create a digital signature.

Public key means the key of a key pair that is used to verify a digital signature. The public key is made available to anyone who will receive digitally signed messages from the holder of the key pair.

Public Key Infrastructure (PKI) means a structure under which a Certification Authority verifies the identity of applicants, issues, renews, and revokes digital certificates, maintains a registry of public keys, and maintains an up-to-date Certificate Revocation List.

SAS 70 Audit means a third-party audit of a technology provider that meets the American Institute of Certified Public Accountants (AICPA) Statement of Auditing Standards (SAS) 70 criteria.

Service provider means a trusted entity that does one or more of the following:

(1) Issues or registers practitioner tokens and issues electronic credentials to practitioners.

(2) Provides the technology system (software or service) used to create and send electronic prescriptions.

(3) Provides the technology system (software or service) used to receive and process electronic prescriptions at a pharmacy.

SysTrust means a professional service performed by a qualified certified public accountant to evaluate one or more aspects of electronic systems.

Token means something a person possesses and controls (typically a key or password) used to authenticate the person's identity.

Valid prescription means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

WebTrust means a professional service performed by a qualified certified public accountant to evaluate one or more aspects of Web sites.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

3. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

4. Section 1304.04 is amended by revising paragraph (b) introductory text, paragraph (b)(1), and paragraph (h) to read as follows:

§ 1304.04 Maintenance of records and inventories.

* * * * *

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not

include executed order forms and inventories, which shall be maintained at each registered location.

* * * * *

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter ''C'' no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs a computer system for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red ''C'' is waived.

(5) Records of electronic prescriptions for controlled substances shall be maintained in a system that meets the requirements of Part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be immediately accessible at the registered location if requested by the Administration or other law enforcement agent. The electronic system must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

* * * * *

PART 1306—PRESCRIPTIONS

5. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

6. Section 1306.05 is revised to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances must be dated as of, and signed on, the day when issued and must bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

(b) A prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for ''detoxification treatment'' or ''maintenance treatment'' must include the identification number issued by the Administrator under § 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of § 1301.28(e).

(c) Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription.

(d) A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions must be written with ink or indelible pencil, typewriter, or printed on a computer printer and must be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed must be manually signed.

(e) Electronic prescriptions must be created and signed using a system that meets the requirements of part 1311 of this chapter.

(f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

(g) An individual practitioner exempted from registration under § 1301.22(c) of this chapter must include on all prescriptions issued by him/her the registration number of the hospital or other institution and the special internal code number assigned to him/her by the hospital or other institution as provided in § 1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each paper prescription must have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(h) An official exempted from registration under § 1301.23(a) must include on all prescriptions issued by him/her his/her branch of service or agency (e.g., ''U.S. Army'' or ''Public Health Service'') and his/her service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his/her Social Security identification number. Each paper prescription must have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

7. Section 1306.08 is added to read as follows:

§ 1306.08 Electronic prescriptions.

(a) An individual practitioner may sign and transmit electronic prescriptions for controlled substances provided the practitioner meets all of the following requirements:

(1) The practitioner must comply with all other requirements for issuing controlled substance prescriptions in this part;

(2) The practitioner must use a system or service provider that meets the requirements of part 1311 of this chapter; and

(3) The practitioner must comply with the requirements for practitioners in part 1311 of this chapter.

(b) A pharmacy may fill an electronically transmitted prescription for a controlled substance provided the pharmacy complies with all other requirements for filling controlled substance prescriptions in this part and with the requirements of part 1311 of this chapter.

(c) To annotate an electronic prescription, a pharmacist must include all of the information required by this part for the record.

(d) If the content of any of the information required under § 1306.05 for a controlled substance prescription is altered during the transmission, the prescription is deemed to be invalid and the pharmacy may not dispense the controlled substance.

8. In § 1306.11, paragraphs (a), (c), (d)(1), and (d)(4) are revised to read as follows:

§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a Schedule II controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A paper prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original paper prescription must be maintained in accordance with § 1304.04(h) of this chapter.

* * * * *

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user.

(d) * * *

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner); * * *

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner must cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1306.05, the prescription must have written on its face ''Authorization for Emergency Dispensing,'' and the date of the oral order. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him/her; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

* * * * *

9. In § 1306.13, paragraph (a) is revised to read as follows:

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

* * * * *

10. In § 1306.15, paragraph (a)(1) is revised to read as follows:

§ 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

* * * * *

(a) * * *

(1) Write the word ''CENTRAL FILL'' on the face of the original paper prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal; for electronic prescriptions the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record.

* * * * *

11. In § 1306.21, paragraphs (a) and (c) are revised to read as follows:

§ 1306.21 Requirement of prescriptions.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

* * * * *

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a paper prescription signed by an individual practitioner, a facsimile of a paper prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

12. Section 1306.22 is revised to read as follows:

§ 1306.22 Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued. No prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times.

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document or electronic prescription record. If entered on another document, such as a medication record, or electronic prescription record, the document or record must be uniformly maintained and readily retrievable.

(c) The following information must be retrievable by the prescription number:

(1) The name and dosage form of the controlled substance.

(2) The date filled or refilled.

(3) The quantity dispensed.

(4) The initials of the dispensing pharmacist for each refill.

(5) The total number of refills for that prescription.

(d) If the pharmacist merely initials and dates the back of the prescription or annotates the electronic prescription record, it shall be deemed that the full face amount of the prescription has been dispensed.

(e) The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original paper prescription or annotates the electronic prescription record with the date, quantity of refill, number of additional refills authorized, and initials the paper prescription or annotates the electronic prescription record showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five refill, six-month limitation.

(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer system may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized system must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized system must also provide online retrieval (via computer monitor or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months.) This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (*e.g.*, J. H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized system shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data are retained for online data entry as soon as the computer system is available for use again.

(g) When filing refill information for original paper, fax, or oral prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs (a) through (e) or (f) of this section.

(h) When filing refill information for electronic prescriptions, a pharmacy must use a system that meets the requirements of part 1311 of this chapter.

13. Section 1306.25 is revised to read as follows:

§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original paper prescription information for a Schedule III, IV, or V controlled substance for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) Electronic prescriptions may be transferred up to the maximum refills

permitted by law and the prescriber's authorization.

(c) Transfers of paper prescriptions are subject to the following requirements:

(1) The transfer must be communicated directly between two licensed pharmacists.

(2) The transferring pharmacist must do the following:

(i) Write the word ''VOID'' on the face of the invalidated prescription.

(ii) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(3) The pharmacist receiving the transferred paper prescription information must write the word ''transfer'' on the face of the transferred prescription and reduce to writing all information required to be on a prescription under § 1306.05 and include:

(i) Date of issuance of original prescription.

(ii) Original number of refills authorized on original prescription.

(iii) Date of original dispensing.

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s).

(v) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

(d) For electronic prescriptions, the transferring pharmacist must do the following:

(1) Add information to the record of the original prescription that indicates the following:

(i) That the prescription has been transferred.

(ii) The name, address, and DEA registration number of the pharmacy to which it was transferred.

(iii) The date of the transfer and the name of the pharmacist transferring the information.

(2) Provide the receiving pharmacy with the following information in addition to the original electronic prescription data:

(i) The date of the original dispensing.

(ii) The number of refills remaining and the dates and location of previous refills.

(iii) The transferring pharmacy's name, address, DEA registration number, and prescription number.

(iv) The name of pharmacist transferring the prescription.

(v) The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

(e) The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription under paragraph (d)(2) of this section.

(f) A transferred electronic prescription may be transferred multiple times, as long as there are refills remaining and as long as the dispensing occurs within six months of the date of issue of the prescription.

(g) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

(h) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.

(i) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

14. Section 1306.28 is added to read as follows:

§ 1306.28 Recordkeeping.

(a) All prescription records required by this part must be maintained as provided in § 1304.04(h) of this chapter.

(b) In addition to any other information required under this part, a pharmacy must retain the following information for each controlled substance prescription filled:

(1) Prescriber's name.

(2) Patient's name and address.

(3) The name and dosage form of the controlled substance.

(4) The quantity dispensed.

(5) The date filled.

(6) The written or typewritten name or initials of the dispensing pharmacist.

(7) The date refilled (Schedule III and IV only).

(8) The total number of refills for the prescription (Schedule III and IV only).

(9) In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with § 1304.26 of this chapter.

PART 1311—REQUIREMENTS FOR ELECTRONIC ORDERS AND PRESCRIPTIONS

15. The authority citation for part 1311 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 829, 871(b), 958(e), 965, unless otherwise noted.

16. The heading for part 1311 is revised to read as set forth above.

17. Section 1311.01 is revised to read as follows:

§ 1311.01 Scope.

This part sets forth the rules governing the creation, transmission, and storage of electronic orders and prescriptions.

18. Section 1311.02 is revised to read as follows:

§ 1311.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Controlled Substance Act (21 U.S.C. 802) or part 1300 of this chapter.

19. In § 1311.08, paragraph (a) is amended by adding paragraph (a)(4) to read as follows:

§ 1311.08 Incorporation by reference.

(a) * * *

(4) NIST SP 800–63, Electronic Authentication Guideline, April 2006.

* * * * *

20. Subpart C, consisting of §§ 1311.100 through 1311.180, is added to read as follows:

Subpart C—Electronic Prescriptions

Sec.
1311.100 Eligibility to issue electronic prescriptions.
1311.105 Electronic prescription system requirements: Identity proofing.
1311.110 Electronic prescription system requirements: Authentication.
1311.115 Electronic prescription system requirements: Prescription contents.
1311.120 Electronic prescription system requirements: Creating a controlled substance prescription.
1311.125 Electronic prescription system requirements: Signing the prescription.
1311.130 Electronic prescription system requirements: Transmission of electronic prescriptions.
1311.135 Electronic prescription system requirements: Revocation of access authorization.
1311.140 Electronic prescription system requirements: Providing log of prescriptions to practitioner.
1311.145 Electronic prescription system requirements: Security incidents.
1311.150 Electronic prescription system requirements: Third-party audits of service provider systems.
1311.155 Practitioner responsibilities.
1311.160 Pharmacy system requirements: Archiving the initial record.
1311.165 Pharmacy system requirements: Prescription processing.

1311.170 Pharmacy system requirements: Security.
1311.175 Pharmacy responsibilities.
1311.180 Recordkeeping.

§ 1311.100 Eligibility to issue electronic prescriptions.

(a) A practitioner may issue a controlled substance prescription electronically if both of the following conditions are met:

(1) The practitioner is registered as an individual practitioner or exempt from registration under part 1301 of this chapter and is authorized under the registration or exemption to dispense the controlled substance.

(2) The practitioner uses an electronic prescription system that meets all of the applicable requirements of this subpart.

(b) An electronic prescription created and transmitted using an electronic prescription system that does not meet the requirements of this subpart is not a valid prescription.

(c) The practitioner issuing an electronic controlled substance prescription is responsible if a prescription does not conform in all essential respects to the law and regulations.

§ 1311.105 Electronic prescription system requirements: Identity proofing.

(a) Before permitting access to the electronic prescription system for signing controlled substance prescriptions, the service provider must receive a document prepared by an entity permitted to conduct in-person identity proofing listed in paragraph (b) of this section. If a practitioner wishes to electronically prescribe controlled substances in more than one State, the service provider must receive a document prepared by an entity permitted to conduct in-person identity proofing that indicates each of the State licenses and DEA Certificates of Registration. Such document shall be prepared either on the identity proofing entity's letterhead or other official form of correspondence, or the service provider may design a form for use by the identity proofing entity. Regardless of the format of the document, the document must contain all of the following information:

(1) The name and DEA registration number, where applicable, of the entity which conducted the in-person identity proofing of the practitioner;

(2) The name of the person within the entity who conducted the in-person identity proofing of the practitioner;

(3) The name and address of the principal place of business of the practitioner whose identity is being verified;

(4)(i) For each State in which the practitioner wishes to prescribe controlled substances electronically, the name of the State licensing authority and State license number of the practitioner whose identity is being verified, or

(ii) If the individual practitioner is an employee of a health care facility that is operated by the Department of Veterans Affairs, confirm that the individual practitioner has been duly appointed to practice at that facility by the Secretary of the Department of Veterans Affairs pursuant to 38 U.S.C. 7401–7408, or

(iii) If the individual practitioner is working at a health care facility operated by the Department of Veterans Affairs on a contractual basis pursuant to 38 U.S.C. 8153 and, in the performance of his duties, prescribes controlled substances, confirm that the individual practitioner meets the criteria for eligibility for appointment under 38 U.S.C. 7401–7408 and is prescribing controlled substances under the registration of such facility;

(5) Except as provided in paragraph (a)(6) of this section, for each State in which the practitioner wishes to prescribe controlled substances electronically, the DEA registration number and date of expiration of DEA registration of the practitioner whose identity is being verified;

(6) For individual practitioners who prescribe controlled substances using the DEA registration of the institutional practitioner, a statement by the institutional practitioner acknowledging the authority of the individual practitioner to prescribe controlled substances using the institution's DEA registration, and the specific internal code number assigned to the individual practitioner;

(7) The type of government-issued photographic identification checked (e.g., the practitioner's driver's license, passport) and a statement that the photograph on the identification matched the person presenting the photographic identification;

(8) The date on which the practitioner's in-person identity proofing was conducted;

(9) The signature of the person within the entity who conducted the in-person identity proofing;

(10) The signature of the practitioner who is the subject of the in-person identity proofing.

(b) The following entities are permitted to conduct in-person identity proofing as described in paragraph (a) of this section:

(1) The entity within a DEA-registered hospital that has previously granted that practitioner privileges at the hospital (e.g., a hospital credentialing office). The practitioner's privileges must be active and in good standing;

(2) The State professional or licensing board or State controlled substances authority that currently authorizes the practitioner to prescribe controlled substances;

(3) A State or local law enforcement agency.

(c) For each practitioner seeking to issue electronic controlled substances prescriptions, the service provider shall do the following:

(1) Check with each State to determine that the practitioner's State license to practice medicine is current and in good standing. If the individual practitioner is an employee of a health care facility that is operated by the Department of Veterans Affairs, the service provider shall confirm that the individual practitioner has been duly appointed to practice at that facility by the Secretary of the Department of Veterans Affairs pursuant to 38 U.S.C. 7401–7408. If the individual practitioner is working at a health care facility operated by the Department of Veterans Affairs on a contractual basis pursuant to 38 U.S.C. 8153 and, in the performance of his duties, prescribes controlled substances, the service provider shall confirm that the individual practitioner meets the criteria for eligibility for appointment under 38 U.S.C. 7401–7408 and is prescribing controlled substances under the registration of such facility.

(2) In those States in which a separate controlled substance registration is required to prescribe controlled substances, check with the appropriate State authority to determine that the practitioner's State license is current and in good standing.

(3) Except for individual practitioners referred to in paragraph (a)(6) of this section, check the DEA CSA database to determine that the DEA registration for each State is current and in good standing;

(4) Ensure that the service provider has an accurate list of the schedules the practitioner is authorized to prescribe;

(5) Contact the prescribing practitioner at the practitioner's registered location by telephone to confirm the practitioner's intent to apply to prescribe controlled substances using the service provider's system. The service provider must obtain the telephone number from a public source other than the application received from the practitioner. Alternatively, the service provider may confirm the practitioner's intent in person at the practitioner's registered location.

(d) The service provider must retain the document referred to in paragraph (a) of this section prepared by the entity that conducted the in-person identity proofing for each practitioner prescribing controlled substances electronically using the service provider's system in the manner specified in § 1311.180 of this part.

§ 1311.110 Electronic prescription system requirements: Authentication.

(a) The system must require that practitioners eligible to issue controlled substance prescriptions use two-factor authentication that meets the requirements of NIST SP 800–63 Level 4 authentication to access the system to sign and transmit controlled substances prescriptions.

(b) The hard token needed to meet NIST SP 800–63 Level 4 authentication must require the entry of a password or biometric to activate the authentication key and must not be able to export the authentication key. The hard token may be a PDA or other handheld device, smart card, thumb drive, etc. The token must be FIPS 140–2 validated as follows:

(1) Overall validation at Level 2 or higher.

(2) Physical security at Level 3 or higher.

(c) The system must require reauthentication if the practitioner does not use the system for more than 2 minutes.

(d) The system must provide a separate authentication protocol for separate DEA registrations. At a minimum, a practitioner must have a separate authentication protocol for each State in which the practitioner holds a DEA registration to dispense controlled substances. The practitioner may store multiple authentication protocols on a single hard token.

(e) The system access authentication protocol must expire no later than the expiration date of the practitioner's DEA registration with which it is associated.

§ 1311.115 Electronic prescription system requirements: Prescription contents.

(a) An electronic prescription for a controlled substance created by the system must include all of the data elements required under paragraph (b) of this section and part 1306 of this chapter.

(b) An electronic prescription for a controlled substance must include all of the following information:

(1) The full name and address of the issuing practitioner.

(2) The DEA registration number of the issuing practitioner. For practitioners issuing prescriptions under a hospital or clinic registration number, the prescription must include the registration number and registrant-assigned extension identifier. For military or Public Health Service practitioners exempt from registration, the prescription must include the practitioner's service identification number or Social Security number as required in § 1306.05(h) of this chapter.

(3) The full name and address of the patient for whom the prescription is written.

(4) The drug name, strength, dosage form, quantity prescribed, and directions for use.

(5) The time and date that the prescription was signed.

(c) An electronic prescription for a controlled substance must have the practitioner name, address, and DEA registration number for only the practitioner issuing the prescription. Multiple DEA registration numbers may not be associated with a prescription.

§ 1311.120 Electronic prescription system requirements: Creating a controlled substance prescription.

(a) The system may allow the registrant or his agent to enter data for a controlled substance prescription.

(b) After the practitioner or his agent has entered the prescription information into the system, the system must display the following information related to the controlled substance prescription:

(1) The patient's name and address.

(2) The name of the drug being prescribed;

(3) The dosage strength and form, quantity, and directions for use.

(4) The DEA registration number under which the prescription will be authorized.

(c) Where more than one controlled substance prescription has been prepared, the practitioner must positively indicate those prescriptions that are to be signed. Any prescription not indicated to be signed shall not be transmitted.

§ 1311.125 Electronic prescription system requirements: Signing the prescription.

(a) The practitioner must authenticate himself to the system using two-factor authentication immediately before signing the prescription. The system may allow a practitioner to sign multiple prescriptions at the same time.

(b) After a practitioner has authenticated to the system but prior to signing the controlled substance prescription, the system must display for the practitioner's review the information required by § 1311.120(b) for all prescriptions that are to be transmitted in connection with that signature. While such information is displayed, the practitioner must be presented with the following statement (or its substantial equivalent): ''I, the prescribing practitioner whose name and DEA registration number appear on the controlled substance prescription(s) being transmitted, have reviewed all of the prescription information listed above and have confirmed that the information for each prescription is accurate. I further declare that by transmitting the prescription(s) information, I am indicating my intent to sign and legally authorize the prescription(s).'' The practitioner must positively indicate agreement with this statement. If the practitioner does not indicate agreement to this statement, the controlled substances prescriptions shall not be transmitted.

(c) The service provider must ensure that its prescription-writing system permits practitioners to sign controlled substance prescriptions only if they have the appropriate State authorization and DEA registration to prescribe the schedule of controlled substances being prescribed.

(d) The system must require that the DEA registrant whose DEA number is listed on the prescription sign the prescription. The system must not allow any other person to sign the prescription.

(e) The signing function may take different names depending on the system and the terms used. Regardless of the system labels, signing is the practitioner's attestation that the prescription is accurate and being issued by the practitioner for a legitimate medical purpose in the usual course of professional practice.

(f) The system must include in the data file transmitted an indication that the prescription was signed by the issuing practitioner.

§ 1311.130 Electronic prescription system requirements: Transmission of electronic prescriptions.

(a) The electronic prescription system must transmit the electronic prescription immediately upon signature by the practitioner.

(b) The electronic prescription system must not allow the printing of an electronic prescription that has been transmitted.

(c) The electronic prescription system must not allow the transmission of an electronic prescription if the prescription has been printed.

(d) The service provider must ensure that the service provider or the first processor of the signed prescription digitally signs a copy of the prescription

as received and archives the digitally signed prescription.

(e) The system must retain the archived digitally signed prescription for five years from the date of issuance by the practitioner.

(f) The contents of the prescription listed in § 1311.115(b) must not be altered during transmission. Any change to the content during transmission will render the prescription invalid. The data may be reformatted.

(g) An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an electronic prescription be converted to another form for transmission.

§ 1311.135 Electronic prescription system requirements: Revocation of access authorization.

(a) The service provider must revoke the authentication protocol used to sign controlled substance prescriptions immediately upon receiving notification from the practitioner that a password or token has been compromised, lost, or stolen.

(b) The service provider must revoke the authentication protocol used to sign controlled substance prescriptions on the expiration date of the practitioner's DEA registration unless the service provider determines that the registration has been renewed.

(c) The service provider must check the DEA CSA database at least once a week and revoke the authentication protocol used to sign controlled substance prescriptions for each practitioner using the system whose registration has been terminated, revoked, or suspended.

§ 1311.140 Electronic prescription system requirements: Providing log of prescriptions to practitioner.

(a) The electronic prescription system must, on a monthly basis, automatically provide the practitioner with an electronic log (which is readily viewable by the practitioner using the system) of all electronic prescriptions for controlled substances that were issued by the practitioner during the previous month using that system.

(b) The electronic prescription system must provide a means for the practitioner to indicate that he has received and reviewed the log.

(c) The electronic prescription system must retain the log provided to the practitioner and a record of the practitioner's indication of the log review for five years.

(d) The electronic prescription system must make available, on the request of the practitioner, a log of all controlled substance prescriptions that the practitioner has transmitted for the previous five years.

§ 1311.145 Electronic prescription system requirements: Security incidents.

(a) The service provider must audit its records and system at least once a day in a manner sufficient to meet the requirements of paragraph (b) of this section.

(b) The service provider must notify the Administration within one business day of any security incidents that indicate that any of the following may have occurred:

(1) An individual who is not a DEA registrant has been granted access to issue controlled substance prescriptions.

(2) An individual has been granted access to issue controlled substance prescriptions without identity proofing that meets the requirements of § 1311.105 of this part.

(3) Access to issue controlled substance prescriptions has been granted to a person using another person's identity.

(4) Prescription records have been created or altered by a service provider employee.

(5) There have been one or more successful attempts to penetrate the service provider's system from the outside.

(6) The service provider has identified any other incident that may indicate that the integrity of the system in regard to controlled substance prescriptions has been compromised.

§ 1311.150 Electronic prescription system requirements: Third-party audits of service provider systems.

(a) The service provider must have a qualified third party conduct an audit that meets the requirements of a WebTrust or SysTrust audit for system security and processing integrity prior to accepting any controlled substances prescriptions for transmission and annually thereafter.

(b) The audit must determine whether the electronic prescription system and the service provider meet the requirements of this part.

(c) The service provider must make the audit report available to any practitioner who uses the system or is considering use of the system. The service provider must retain each annual audit report for the last five years.

(d) If the third-party audit finds that the system does not meet one or more of the requirements of this part or does not provide adequate security against insider and outsider threats, the service provider must not accept for transmission any controlled substance prescription. The service provider must notify practitioners that they should not use the system to generate and transmit controlled substance prescriptions. The service provider must also notify the Administration of the adverse audit report and provide the report to the Administration.

(e) For service providers that install the prescription-writing system on a practitioner's computers and that are not involved in the subsequent transmission of the prescription, the service provider must notify its DEA registrant customers of the results of any third-party audit that finds that the system does not meet one or more of the requirements of this part. The service provider must also notify the Administration of the adverse audit report and provide the report to the Administration.

§ 1311.155 Practitioner responsibilities.

(a) The practitioner shall provide, or cause to be provided, to the service provider a document from an entity permitted to conduct in-person identity proofing that meets the requirements of § 1311.105 of this part.

(b) The practitioner must retain sole possession of the hard token and must not share the password with any other person. The practitioner must not allow any other person to use the token or enter the password or other identification means to sign prescriptions for controlled substances. Failure by the practitioner to secure the hard token or password may provide a basis for revocation or suspension of registration pursuant to section 304(a)(4) of the Act (21 U.S.C. 824(a)(4)).

(c) The practitioner must notify the service provider within 12 hours of discovery that the hard token has been lost, stolen, or compromised. A practitioner who fails to notify the service provider of the loss, theft, or compromise of the hard token will be held responsible for any controlled substance prescriptions written using the hard token.

(d) The practitioner must review the monthly log to determine whether the prescriptions issued under his DEA registration number were, in fact, issued by him and whether any prescriptions appear to be unusual based on the practitioner's known prescribing pattern. The practitioner must indicate on the log that he has reviewed it. Practitioners are not required to check the log against patient records.

(e) The practitioner must notify both the service provider and the Administration within 12 hours of

discovery that one or more prescriptions that were issued under his DEA registration were prescriptions he had not signed or were not consistent with the prescription he signed.

(f) The practitioner must determine initially and at least annually thereafter that the third-party audit report of the service provider indicates that the system and service provider meet the requirements of this part. If the third-party audit report indicates that the system or the service provider does not meet the requirements of this part, or the service provider notifies the practitioner that the system does not meet the requirements of this part, the practitioner must immediately cease to issue electronic controlled substance prescriptions using the system.

(g) The practitioner has the same responsibilities when issuing prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription. Nothing in this part relieves a practitioner of his responsibility to dispense controlled substances only for a legitimate medical purpose while acting in the usual course of his professional practice. If an agent enters information at the practitioner's direction prior to the practitioner reviewing and approving the information and signing and authorizing the transmission of that information, the practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.

§ 1311.160 Pharmacy system requirements: Archiving the initial record.

(a) A copy of each electronic controlled substance prescription record that a pharmacy receives must be digitally signed by one of the following:

(1) The last intermediary transmitting the record to the pharmacy immediately prior to transmission to the pharmacy.

(2) The first pharmacy system that receives the electronic prescription immediately on receipt.

(b) If the last intermediary digitally signs the record, it must forward the digitally signed copy to the pharmacy.

(c) The pharmacy system must archive and retain the digitally signed prescription as received for five years from the date of receipt.

§ 1311.165 Pharmacy system requirements: Prescription processing.

(a) The pharmacy system must verify that the practitioner's DEA registration was valid at the time the prescription was signed. The pharmacy system may do this by checking the DEA CSA database or by having the prescribing practitioner's service provider or one of the intermediaries check the DEA CSA database during transmission and indicate on the record that the check has occurred and the registration is valid. The CSA database may be cached for one week from the date of issuance.

(b) The pharmacy system must verify that the practitioner signed the prescription by checking the data field that indicates the prescription was signed.

(c) The pharmacy system must reject any of the following controlled substance prescriptions:

(1) A prescription that was not signed.

(2) A prescription that was signed by a practitioner without a valid DEA registration.

(3) A prescription that does not include all of the information required under § 1306.05 of this chapter.

(d) The pharmacy system must be capable of reading and retaining the full DEA registration number, including any extensions, or other identification numbers used under § 1306.05(c) of this chapter. The full number including extensions must be retained in the prescription record.

(e) The pharmacy system must provide for the following information to be added or linked to each controlled substance prescription record for each dispensing, as required in §§ 1304.22(c) and 1306.22 of this chapter:

(1) The number of units or volume of the controlled substance dispensed.

(2) The date of the dispensing.

(3) The full name of the person who dispensed the prescription.

(4) The number of refills allowed.

(f) The pharmacy system must be capable of retrieving information on controlled substance prescriptions by the following data:

(1) Prescriber name.

(2) Patient name.

(3) Drug dispensed.

(4) Date dispensed.

(g) The pharmacy prescription system must be capable of downloading an electronic copy of controlled substance prescription records into a database or spreadsheet format that is readily readable and can be easily sorted by the data elements listed in paragraph (f) of this section. Such database or spreadsheet must be able to be printed or provided electronically without the need for additional specialized software.

§ 1311.170 Pharmacy system requirements: Security.

(a) The pharmacy system must create and maintain a backup copy of all controlled substance prescriptions at an alternate storage site that is geographically separated from the primary storage site so as not to be susceptible to the same hazards. A copy of each digitally signed controlled substance prescription and all linked dispensing records must be transferred to the backup storage site at least once every 24 hours. Backup copies must be maintained for five years from the date of the record creation.

(b) The pharmacy system must create and maintain an internal audit trail that indicates each time a controlled substance prescription file is opened, annotated, altered, or deleted and the identity of the person taking the action. The audit trail records must be maintained for five years.

(c) The pharmacy or the service provider must establish and implement a list of auditable events. The auditable events must, at a minimum, include attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in the prescription system.

(d) The system must analyze the audit logs at least once every 24 hours and generate an incident report that identifies each auditable event.

(e) The pharmacy must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the service provider and the Administration within one business day.

(f) The pharmacy system must have a qualified third party conduct an audit that meets the requirements of a SysTrust or SAS 70 audit for system security and processing integrity prior to accepting any controlled substances prescriptions for processing and annually thereafter.

(g) The third-party audit must determine whether the system for processing controlled substance prescriptions and the service provider meet the requirements of this part. The service provider must make the audit report available to any pharmacy who uses the system. The service provider must retain each annual audit report for the last five years.

(h) If the third-party audit finds that the system does not meet one or more of the requirements of this part or does not provide adequate security against insider and outsider threats, the system must not accept or process any electronic controlled substance prescription. The service provider must notify pharmacies that they should not use the system to accept and process controlled substance prescriptions. The service provider must also notify the Administration of the adverse audit

report and provide the report to the Administration.

(i) For service providers that install the prescription-processing system on a pharmacy's computers and that are not involved in the subsequent acceptance and processing of the prescription, the service provider must notify its DEA registrant customers of the results of any third-party audit that finds that the system does not meet one or more of the requirements of this part. The service provider must also notify the Administration of the adverse audit report and provide the report to the Administration.

§ 1311.175 Pharmacy responsibilities.

(a) A pharmacy must not dispense controlled substances in response to electronic controlled substance prescriptions if its pharmacy system or service provider does not meet the requirements of this part.

(b) A pharmacy must not process electronic controlled substance prescriptions if the DEA registration of the prescriber was not valid at the time the prescription was signed or if the system rejected the prescription for any other reason.

(c) When a pharmacist fills a prescription in a manner that would require, under part 1306 of this chapter, the pharmacist to make a notation on the prescription if the prescription were a paper prescription, the pharmacist must make such notation electronically when filling an electronic prescription.

(d) Nothing in this part relieves a pharmacy of its responsibility to dispense controlled substances only pursuant to a prescription issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

§ 1311.180 Recordkeeping.

(a) A practitioner, pharmacy, or service provider must maintain records required by this part for electronic prescriptions for five years from their creation. Records may be maintained electronically. Records regarding controlled substances prescriptions that are maintained electronically must be readily retrievable from all other records.

(b) This record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies.

(c) Electronic records must be easily readable or easily rendered into a format that a person can read. They must be made available to the Administration upon request.

21. Subpart D, consisting of §§ 1311.200 through 1311.280, is added to read as follows:

Subpart D—Electronic Prescriptions for Federal Agencies

Sec.

1311.200 Eligibility to digitally sign electronic prescriptions.
1311.205 Issuance and storage of digital certificates.
1311.210 Digitally signed prescription system requirements: Prescription-writing system requirements.
1311.215 Digitally signed prescription system requirements: Prescription contents.
1311.220 Digitally signed prescription system requirements: Creating a controlled substance prescription.
1311.225 Digitally signed prescription system requirements: Signing the prescription.
1311.230 Digitally signed prescription system requirements: Transmission of electronic prescriptions.
1311.235 Digitally signed prescription system requirements: Revocation of access authorization.
1311.245 Digitally signed prescription system requirements: Security incidents.
1311.250 Digitally signed prescription system requirements: Third-party audits of systems.
1311.255 Practitioner responsibilities.
1311.260 Pharmacy system requirements: Archiving the initial record.
1311.265 Pharmacy system requirements: Prescription processing.
1311.270 Pharmacy system requirements: Security.
1311.275 Pharmacy responsibilities.
1311.280 Recordkeeping.

§ 1311.200 Eligibility to digitally sign electronic prescriptions.

(a) As an optional alternative to issuing electronic prescriptions for controlled substances under the conditions set forth in Subpart C of this part, a practitioner prescribing controlled substances at a Federal health care facility in the course of their official duties may issue a controlled substance prescription electronically under the conditions set forth in this subpart if both of the following conditions are met:

(1) The practitioner is registered as an individual practitioner or exempt from registration under part 1301 of this chapter and is authorized under the registration or exemption to dispense the controlled substance.

(2) The practitioner uses an electronic prescription system that meets all of the applicable requirements of this subpart.

(b) For purposes of this section, the term ''Federal health care facility'' means a hospital or other institution that is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Department of Veterans Affairs, Public Health Service, or Bureau of Prisons).

(c) An electronic prescription created and transmitted using an electronic prescription system that does not meet the requirements of this subpart is not a valid prescription.

(d) The practitioner issuing an electronic controlled substance prescription is responsible if a prescription does not conform in all essential respects to the law and regulations.

§ 1311.205 Issuance and storage of digital certificates.

(a) Only Federal Certification Authorities or Certification Authorities cross-certified with a Certification Authority operated by the Federal Public Key Infrastructure Policy Authority may issue digital certificates to practitioners prescribing controlled substances at a Federal health care facility in the course of their official duties to sign electronic controlled substance prescriptions.

(b) The digital certificate must be stored on a hardware token that meets the requirements of NIST SP 800–63 Level 4.

§ 1311.210 Digitally signed prescription system requirements: Prescription-writing system requirements.

(a) Any system may be used to digitally sign electronic prescriptions for controlled substances provided that the system has been enabled to accept digitally signed documents and that it meets the following requirements:

(1) The cryptographic module must be FIPS 140–2 level 1 validated.

(2) The digital signature system and hash function must comply with FIPS 186–2 and FIPS 180–1.

(3) The private key must be stored encrypted on a FIPS 140–2 level 1 validated cryptographic module using a FIPS-approved encryption algorithm.

(4) For software implementations, when the signing module is deactivated, the system must clear the plain text password from the system memory to prevent the unauthorized access to, or use of, the private key.

(5) The system must have a time system that is within five minutes of the official National Institute of Standards and Technology time source.

(b) The system must require that practitioners eligible to issue controlled substance prescriptions use two-factor authentication that meets the requirements of NIST SP 800–63 Level

4 authentication to access the system to sign and transmit controlled substances prescriptions.

(c) The hard token needed to meet NIST SP 800–63 Level 4 authentication must require the entry of a password or biometric to activate the authentication key and must not be able to export the authentication key. The token must be FIPS 140–2 validated as follows:

(1) Overall validation at Level 2 or higher.

(2) Physical security at Level 3 or higher.

(d) The system must require reauthentication if the practitioner does not use the system for more than 2 minutes.

§ 1311.215 Digitally signed prescription system requirements: Prescription contents.

A digitally signed electronic prescription for a controlled substance created by the system must include all of the data elements required under part 1306 of this chapter.

§ 1311.220 Digitally signed prescription system requirements: Creating a controlled substance prescription.

(a) The system may allow the registrant or his agent to enter data for a controlled substance prescription.

(b) After the practitioner or his agent has entered the prescription information into the system, the system must display the following information related to the controlled substance prescription:

(1) The patient's name and address;

(2) The name of the drug being prescribed;

(3) The dosage strength and form, quantity, and directions for use;

(4) The DEA registration number under which the prescription will be authorized.

(c) Where more than one controlled substance prescription has been prepared, the practitioner must positively indicate those prescriptions that are to be signed. Any prescription not indicated to be signed shall not be transmitted.

§ 1311.225 Digitally signed prescription system requirements: Signing the prescription.

(a) The practitioner must authenticate himself to the system using two-factor authentication immediately before signing the prescription. The system may allow a practitioner to sign multiple prescriptions at the same time.

(b) After a practitioner has authenticated to the system but prior to signing the controlled substance prescription, the system must display for the practitioner's review the information required by § 1311.220(b) for all prescriptions that are to be transmitted in connection with that signature. While such information is displayed, the practitioner must be presented with the following statement (or its substantial equivalent): ''I, the prescribing practitioner whose name and DEA registration number appear on the controlled substance prescription(s) being transmitted, have reviewed all of the prescription information listed above and have confirmed that the information for each prescription is accurate. I further declare that by transmitting the prescription(s) information, I am indicating my intent to sign and legally authorize the prescription(s).'' The practitioner must positively indicate agreement with this statement. If the practitioner does not indicate agreement to this statement, the controlled substances prescriptions shall not be transmitted.

(c) The Federal agency must ensure that its prescription-writing system permits practitioners to digitally sign controlled substance prescriptions only if they have the appropriate authorization to prescribe the schedule of controlled substances being prescribed.

(d) The system must require that the DEA registrant whose DEA number is listed on the prescription digitally sign the prescription. The system must not allow any other person to sign the prescription.

(e) The system must check the certificate revocation list of the Certification Authority that issued the digital certificate of the practitioner who digitally signed the controlled substance prescription. If the certificate is not valid, the system must not transmit the prescription. The certificate revocation list may be cached until the Certification Authority issues a new certificate revocation list.

(f) If the prescription is being transmitted to a pharmacy that does not accept digitally signed prescriptions, the system must include in the data file transmitted an indication that the prescription was signed by the issuing practitioner.

§ 1311.230 Digitally signed prescription system requirements: Transmission of electronic prescriptions.

(a) The electronic prescription system must not allow the printing of an electronic prescription that has been transmitted.

(b) The electronic prescription system must not allow the transmission of an electronic prescription if the prescription has been printed.

(c) The system must retain the archived digitally signed prescription for five years from the date of issuance by the practitioner.

(d) The data elements required under part 1306 of this chapter must not be altered during transmission. Any change to the content during transmission will render the prescription invalid. The data may be reformatted.

(e) An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an electronic prescription be converted to another form for transmission.

§ 1311.235 Digitally signed prescription system requirements: Revocation of access authorization.

(a) The system must revoke access to sign controlled substance prescriptions on the expiration date of the practitioner's DEA registration, if applicable, unless the Federal agency determines that the registration or Federal agency authorization has been renewed.

(b) The system must check the DEA CSA database at least once a week and revoke access to signing controlled substance prescriptions for any practitioner using the system whose registration or Federal agency authorization has been terminated, revoked, or suspended.

§ 1311.245 Digitally signed prescription system requirements: Security incidents.

(a) The Federal agency must audit its controlled substance prescription electronic records and system at least once a day in a manner sufficient to meet the requirements of paragraph (b) of this section.

(b) The Federal agency must notify the Administration within one business day of any security incidents that indicate that any of the following may have occurred:

(1) An individual who is not a DEA registrant authorized by the Federal agency to prescribe controlled substances in the course of their official duties at the Federal agency has been granted access to issue controlled substance prescriptions.

(2) Access to issue controlled substance prescriptions has been granted to a person using another person's identity.

(3) Prescription records have been created or altered by an employee not authorized to create or annotate a controlled substance record.

(4) There have been one or more successful attempts to penetrate the system from the outside.

(5) The Federal agency has identified any other incident that may indicate that the integrity of the system in regard

to controlled substance prescriptions has been compromised.

§ 1311.250 Digitally signed prescription system requirements: Third-party audits of systems.

(a) The Federal agency must have a third-party audit to verify that the system used to create and transmit controlled substance prescriptions meets the requirements of this subpart prior to accepting any controlled substances prescriptions for transmission and annually thereafter.

(b) The Federal agency must retain each annual audit report for the last five years.

(c) If the third-party audit finds that the system does not meet one or more of the requirements of this part, the system must not accept for transmission any controlled substance prescription. The Federal agency must also notify the Administration of the adverse audit report and provide the report to the Administration.

§ 1311.255 Practitioner responsibilities.

(a) The practitioner must retain sole possession of the hard token and must not share the password with any other person. The practitioner must not allow any other person to use the token or enter the password or other identification means to sign prescriptions for controlled substances. Failure by the practitioner to secure the hard token or password may provide a basis for revocation or suspension of registration pursuant to section 304(a)(4) of the Act (21 U.S.C. 824(a)(4)).

(b) The practitioner must notify the Certification Authority within 12 hours of discovery that the hard token has been lost, stolen, or compromised. A practitioner who fails to notify the Certification Authority of the loss, theft, or compromise of the hard token will be held responsible for any controlled substance prescriptions written using the hard token.

(c) The practitioner has the same responsibilities when issuing prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription. Nothing in this part relieves a practitioner of his responsibility to dispense controlled substances only for a legitimate medical purpose while acting in the usual course of his professional practice. If an agent enters information at the practitioner's direction prior to the practitioner reviewing and approving the information and signing and authorizing the transmission of that information, the practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.

§ 1311.260 Pharmacy system requirements: Archiving the initial record.

(a) If a pharmacy receives a controlled substance prescription from a Federal agency system that is not transmitted with its digital signature, either the pharmacy must digitally sign the prescription immediately upon receipt, or the last intermediary transmitting the record to the pharmacy must digitally sign the prescription immediately prior to transmission and transmit to the pharmacy the prescription and the digitally signed record. The pharmacy must archive the record as received and the digitally signed copy.

(b) If a Federal pharmacy receives a digitally signed prescription that includes the digital signature, the pharmacy must validate the prescription and archive the digitally signed record. The pharmacy record must retain an indication that the prescription was validated upon receipt. No additional digital signature is required.

(c) The pharmacy system must retain the digitally signed prescription as received for five years from the date of receipt.

§ 1311.265 Pharmacy system requirements: Prescription processing.

(a) The pharmacy system must verify that the practitioner's DEA registration was valid at the time the prescription was signed. The pharmacy system may do this by checking the DEA CSA database or by having the prescribing practitioner's system or one of the intermediaries check the DEA CSA database during transmission and indicate on the record that the check has occurred and the registration is valid. The CSA database may be cached for one week from the date of issuance.

(b) If the digital signature is not part of the record, the pharmacy system must verify that the practitioner signed the prescription by checking the data field that indicates the prescription was signed.

(c) The pharmacy system must reject any of the following controlled substance prescriptions:

(1) A prescription that was signed by a practitioner without a valid DEA registration.

(2) A prescription that does not include all of the information required under § 1306.05 of this chapter.

(3) If the digital signature is received, a prescription that is not validated.

(d) The pharmacy system must be capable of reading and retaining the full DEA registration number, including any extensions, or other identification numbers used under § 1306.05(c) of this chapter. The full number including extensions must be retained in the prescription record.

(e) The pharmacy system must provide for the following information to be added or linked to each controlled substance prescription record for each dispensing, as required in §§ 1304.22(c) and 1306.22 of this chapter:

(1) The number of units or volume of the controlled substance dispensed.

(2) The date of the dispensing.

(3) The full name of the person who dispensed the prescription.

(4) The number of refills allowed.

(f) The pharmacy system must be capable of retrieving information on controlled substance prescriptions by the following data:

(1) Prescriber name.

(2) Patient name.

(3) Drug dispensed.

(4) Date dispensed.

(g) The pharmacy prescription system must be capable of downloading an electronic copy of controlled substance prescription records into a database or spreadsheet format that is readily readable and can be easily sorted by the data elements listed in paragraph (f) of this section. Such database or spreadsheet must be able to be printed or provided electronically without the need for additional specialized software.

§ 1311.270 Pharmacy system requirements: Security.

(a) The pharmacy system must create and maintain a backup copy of all controlled substance prescriptions at an alternate storage site that is geographically separated from the primary storage site so as not to be susceptible to the same hazards. A copy of each digitally signed controlled substance prescription and all linked dispensing records must be transferred to the backup storage site at least once every 24 hours. Backup copies must be maintained for five years from the date of the record creation.

(b) The pharmacy system must create and maintain an internal audit trail that indicates each time a controlled substance prescription file is opened, annotated, altered, or deleted and the identity of the person taking the action. The audit trail records must be maintained for five years.

(c) The pharmacy must establish and implement a list of auditable events. The auditable events must, at a minimum, include attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in the prescription system.

(d) The system must analyze the audit logs at least once every 24 hours and generate an incident report that identifies each auditable event.

(e) The pharmacy must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the Federal agency and the Administration within one business day.

(f) The Federal agency must have a qualified third party conduct an audit for processing integrity prior to accepting any controlled substances prescriptions for processing and annually thereafter.

(g) The third-party audit must determine whether the system for processing controlled substance prescriptions meets the requirements of this part. The Federal agency must retain each annual audit report for the last five years.

(h) If the third-party audit finds that the system does not meet one or more of the requirements of this part, the system must not accept or process any electronic controlled substance prescription. The Federal agency must also notify the Administration of the adverse audit report and provide the report to the Administration.

§ 1311.275 Pharmacy responsibilities.

(a) A pharmacy must not dispense controlled substances in response to electronic controlled substance prescriptions if its pharmacy system does not meet the requirements of this part.

(b) A pharmacy must not process electronic controlled substance prescriptions if the DEA registration or agency authorization of the prescriber was not valid at the time the prescription was signed or if the system rejected the prescription for any other reason.

(c) When a pharmacist fills a prescription in a manner that would require, under part 1306 of this chapter, the pharmacist to make a notation on the prescription if the prescription were a paper prescription, the pharmacist must make such notation electronically when filling an electronic prescription.

(d) Nothing in this part relieves a pharmacy of its responsibility to dispense controlled substances only pursuant to a prescription issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

§ 1311.280 Recordkeeping.

(a) A Federal agency or pharmacy must maintain records required by this part for electronic prescriptions for five years from their creation. Records may be maintained electronically. Records regarding controlled substances prescriptions that are maintained electronically must be readily retrievable from all other records.

(b) This record retention requirement shall not preempt any longer period of retention which may be required now or in the future, by any other federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies.

(c) Electronic records must be easily readable or easily rendered into a format that a person can read. They must be made available to the Administration upon request.

Dated: June 6, 2008.

Michele M. Leonhart,

Acting Administrator.

[FR Doc. E8–14405 Filed 6–26–08; 8:45 am]

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Federal Register

Friday,
June 27, 2008

Part V

The President

Proclamation 8271—Termination of the Exercise of Authorities Under the Trading With the Enemy Act With Respect to North Korea

Executive Order 13466—Continuing Certain Restrictions With Respect to North Korea and North Korean Nationals

Federal Register
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Presidential Documents

Title 3—

The President

Proclamation 8271 of June 26, 2008

Termination of the Exercise of Authorities Under the Trading With the Enemy Act With Respect to North Korea

By the President of the United States of America

A Proclamation

I, GEORGE W. BUSH, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, including section 101(b) of Public Law 95–223 (91 Stat. 1625; 50 U.S.C. App. 5(b) note), hereby find that the continuation of the exercise of authorities under the Trading With the Enemy Act (50 U.S.C. App. 1 *et seq.*) (TWEA) with respect to North Korea, as authorized in Proclamation 2914 of December 16, 1950, most recently continued under Presidential Determination 2007–32 of September 13, 2007 (72 *FR* 53407), and implemented by the regulations set forth below, is no longer in the national interest of the United States.

Section 1. The exercise of TWEA authorities with respect to North Korea, which were implemented by the Foreign Assets Control Regulations, 31 C.F.R. part 500, and the Transaction Control Regulations, 31 C.F.R. part 505, and that were continued by Presidential Determination 2007–32 of September 13, 2007, is terminated, and Presidential Determination 2007–32 is rescinded with respect to North Korea.

Sec. 2. The Secretary of the Treasury is authorized and directed to take all appropriate measures within the Secretary's authority to give effect to this proclamation.

Sec. 3. This proclamation is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, instrumentalities, or entities, its officers or employees, or any other person.

Sec. 4. This proclamation is effective at 12:01 a.m. eastern daylight time on June 27, 2008.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-sixth day of June, in the year of our Lord two thousand eight, and of the Independence of the United States of America the two hundred and thirty-second.

[FR Doc. 08–1398
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Presidential Documents

Executive Order 13466 of June 26, 2008

Continuing Certain Restrictions With Respect to North Korea and North Korean Nationals

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), and section 301 of title 3, United States Code,

I, GEORGE W. BUSH, President of the United States of America, find that the current existence and risk of the proliferation of weapons-usable fissile material on the Korean Peninsula constitute an unusual and extraordinary threat to the national security and foreign policy of the United States, and I hereby declare a national emergency to deal with that threat. I further find that, as we deal with that threat through multilateral diplomacy, it is necessary to continue certain restrictions with respect to North Korea that would otherwise be lifted pursuant to a forthcoming proclamation that will terminate the exercise of authorities under the Trading With the Enemy Act (50 U.S.C. App. 1 *et seq.*) (TWEA) with respect to North Korea.

Accordingly, I hereby order:

Section 1. Except to the extent provided in statutes or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted prior to the date of this order, the following are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

all property and interests in property of North Korea or a North Korean national that, pursuant to the President's authorities under the TWEA, the exercise of which has been continued in accordance with section 101(b) of Public Law 95–223 (91 Stat. 1625; 50 U.S.C. App. 5(b) note), were blocked as of June 16, 2000, and remained blocked immediately prior to the date of this order.

Sec. 2. Except to the extent provided in statutes or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted prior to the date of this order, United States persons may not register a vessel in North Korea, obtain authorization for a vessel to fly the North Korean flag, or own, lease, operate, or insure any vessel flagged by North Korea.

Sec. 3. (a) Any transaction by a United States person or within the United States that evades or avoids, has the purpose of evading or avoiding, or attempts to violate any of the prohibitions set forth in this order is prohibited.

(b) Any conspiracy formed to violate any of the prohibitions set forth in this order is prohibited.

Sec. 4. For the purposes of this order:

(a) the term ''person'' means an individual or entity;

(b) the term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization; and

(c) the term ''United States person'' means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

Sec. 5. The Secretary of the Treasury, after consultation with the Secretary of State, is hereby authorized to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the United States Government consistent with applicable law. All agencies of the United States Government are hereby directed to take all appropriate measures within their authority to carry out the provisions of this order.

Sec. 6. The Secretary of the Treasury, after consultation with the Secretary of State, is hereby authorized to submit the recurring and final reports to the Congress on the national emergency declared in this order, consistent with section 401(c) of the NEA (50 U.S.C. 1641(c)) and section 204(c) of IEEPA (50 U.S.C. 1703(c)).

Sec. 7. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, instrumentalities, or entities, its officers or employees, or any other person.

THE WHITE HOUSE,
June 26, 2008.

[FR Doc. 08–1399
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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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HEALTH AND HUMAN SERVICES DEPARTMENT

Centers for Medicare & Medicaid Services

Medicare and Medicaid Programs:

Hospital Conditions of Participation; Laboratory Services; published 6-27-08

Medicare Program:

Medicare Part D Claims Data; published 5-28-08

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Class E Airspace; Amendment:

Gettysburg, PA; published 6-27-08

Indianapolis, IN; published 6-27-08

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Internal Revenue Service

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Coast Guard

Drawbridge Operation Regulations:

Long Island, NY Inland Waterway from East Rockaway Inlet to Shinnecock Canal, Hempstead, NY, Public Event; published 6-19-08

Safety Zone:

Sigma Financial Fireworks, Lake Huron, Mackinac Island, MI; published 6-23-08

Washington Township Summerfest, Ottawa River, Toledo, OH; published 6-26-08

Safety Zone; Erie Summer Festival of the Arts, Presque Isle Bay, Erie, PA; published 6-27-08

Safety Zones: Weymouth 4th of July Fireworks; Port of Boston; published 5-15-08

Special Local Regulations:

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Arlington Chamber of Commerce Fireworks Display, Arlington, OR; published 6-19-08

RULES GOING INTO EFFECT JUNE 29, 2008

TRANSPORTATION DEPARTMENT

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Disclosure of Rail Interchange Commitments; published 5-30-08

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Forest Service

Subsistence Management Regulations for Public Lands in Alaska; (2009 and 2010 and 2010-2011):

Subsistence Taking of Fish and Shellfish Regulations; comments due by 6-30-08; published 4-17-08 [FR E8-07841]

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Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic:

Shrimp Fishery of the Gulf of Mexico; Revisions to Allowable Bycatch Reduction Devices; comments due by 7-3-08; published 6-3-08 [FR E8-12324]

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ENVIRONMENTAL PROTECTION AGENCY

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Minnesota; Interstate Transport of Pollution; comments due by 7-2-08; published 6-2-08 [FR E8-12222]

Minnesota; Maintenance Plan Update for Dakota County Lead Area; comments due by 7-3-08; published 6-3-08 [FR E8-12240]

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Reasonably Available Control Technology Under the 8-Hour Ozone National Ambient Air Quality Standard; comments due by 6-30-08; published 5-30-08 [FR E8-12122]

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Variance Determination for Particulate Matter from a Specific Source in the State of New Jersey; comments due by 6-30-08; published 5-29-08 [FR E8-11979]

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Florida and South Carolina; Open for comments until further notice; published 2-11-08 [FR 08-00596]

Method 207 - Pre-Survey Procedure for Corn Wet-Milling Facility Emission Sources; comments due by 6-30-08; published 5-29-08 [FR E8-11882]

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HEALTH AND HUMAN SERVICES DEPARTMENT

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HOMELAND SECURITY DEPARTMENT

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Fish and Wildlife Service

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

S. 2420/P.L. 110–247

Federal Food Donation Act of 2008 (June 20, 2008; 122 Stat. 2314)

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